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**DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INNOVATION
COMMITTEE ON CONSUMER POLICY**

Working Party on Consumer Product Safety

**REPORT ON INTERNATIONAL CONSUMER PRODUCT SAFETY RISK ASSESSMENT
PRACTICES**

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FOREWORD

On 23 March 2015, on behalf of the OECD Working Party on Consumer Product Safety (WP), Health Canada launched a survey examining the use of risk assessment by WP member authorities in their decision-making processes [[DSTI/CP/CPS\(2015\)11](#)].

The attached report, which was commissioned by Health Canada and prepared by Bruce Farquhar, consultant, provides a summary of the survey results and explores the similarities and unique approaches to assessing risk across jurisdictions.

At its 12th Session in April 2016, the WP approved the submission of the report to the Committee on Consumer Policy (CCP) for its declassification under the written process, which took place on **12 July 2016**.

The document is published on the responsibility of the Secretary-General of the OECD.

EXECUTIVE SUMMARY

This report provides a summary of the results of a survey launched on 23 March 2015 by Health Canada, on behalf of the OECD Working Party on Consumer Product Safety (WP), to examine the use of risk assessment by authorities in their decision-making processes. Based on the responses received from twenty-one countries between April and June 2015, the report explores the similarities and unique approaches to assessing risk across jurisdictions.

The structure of the survey findings includes: i) a general overview of risk assessment and risk management; ii) the use of risk assessment in different stages of a product safety cycle; and iii) ideas for work that the WP may wish to further develop on risk assessment in the future.

The survey results may be summarised as follows:

- Most jurisdictions reported that risk assessment or specific safety requirements play a role in their decision making.
- A few countries have pre-market approvals.
- The majority of countries reported on the use of some form of risk profiles during border and customs checks.
- Risk assessment plays an important role in marketplace surveillance, enforcement and communication activities.

With respect to any future work on risk assessment, survey participants highlighted ongoing interest in the issue of quality of data, probability factors, and injury scenarios; new areas of interest identified included market surveillance, enforcement actions, and setting regulations and standards. With this in mind, at its October 2015 meeting, the WP examined ways in which its work programme for 2016, and for the 2017-2018 biennium, may be prioritised, and requested its Bureau to agree on any possible next steps on risk assessment. At its November 2015 teleconference, the WP Bureau decided to suspend work on risk assessment through to the end of 2018. It agreed that the survey results would be used by the WP to re-assess its interest in any potential future work on risk assessment after 2018.

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REPORT ON INTERNATIONAL CONSUMER PRODUCT SAFETY RISK ASSESSMENT PRACTICES

Background

Since 2012, the OECD Working Party on Consumer Product Safety (WP) has been developing work on risk assessment, focusing on the types of actions required to reduce the injury risks faced by consumers using products. As part of the project, two workshops were held in, respectively, Israel (in 2012) and Australia (in 2013). A summary of the events proceedings, prepared by the Australian Competition and Consumer Commission (ACCC), and declassified by the Committee on Consumer Policy at its 90th Session in October 2015 [[DSTI/CP/CPS\(2014\)6/FINAL](#)], revealed that risk assessment had different meanings across different jurisdictions and that it was increasingly used by product safety authorities to help inform a number of their decisions at different stages of a product safety cycle. In follow up to the events, and based on a proposal from Health Canada discussed at the WP's 9th Session in October 2014, a survey was launched on 23 March 2015 to examine the general considerations taken into account by authorities in different jurisdictions when assessing risk and to identify the tools available and used by the authorities in their risk assessment process (Annex A - [[DSTI/CP/CPS\(2015\)11](#)]).

This report, commissioned by Health Canada, provides a summary of the survey results and takes a broader view of risk assessment by looking at the assessment of risks by authorities at different stages of the product safety cycle. It also aims to identify possible new areas of work on risk assessment that the WP may wish to explore in the future.

The Survey

The survey, whose structure aimed to reflect the different stages of a product safety cycle where regulators may be conducting an assessment of risks, was divided into three main parts providing: *i*) a general overview of risk assessment and risk management; *ii*) a description of the different stages of a product safety cycle, which included regulations and standards, pre-market controls, including inspection at economic operators' premises,¹ border and customs checks, market surveillance and enforcement actions, as well as any other procedures and tools used in jurisdictions; and *iii*) ideas for future work that the WP may wish to further develop. To facilitate more focused qualitative responses, the survey included some explanatory text, as well as examples of risk assessment processes carried out in some jurisdictions. This report is structured along the lines of the survey.

Participants

The survey was initially circulated to the WP and then presented by Health Canada at a virtual symposium held on 2 April 2015. During the webinar, Health Canada also provided an overview of their new *Risk Assessment Framework* as an example of how certain jurisdictions might articulate their

¹ For the purpose of this report, the terms "economic operator" mean a party involved in the international movement of goods in whatever function that has been approved by, or on behalf of, a national customs administration as complying with World Customs Organisation or equivalent supply chain security standards.

approach to assessing risks. The survey was subsequently circulated to the members of the Product Safety Forum of Europe (PROSAFE)² Risk Assessment Group.

Between April and June 2015, responses from the following twenty-one regulators were received: Australia, Bosnia and Herzegovina, Brazil, Canada, Colombia, Czech Republic, Denmark, the European Commission, Finland, France, Germany, Israel, Japan, the Netherlands, New Zealand, the Russian Federation, Singapore, Slovakia, Slovenia, Turkey and the United States. The responding authorities are listed in Table 1 below.

Table 1. List of regulatory agencies that participated in the survey

Australia	Australian Competition and Consumer Commission (ACCC)
Bosnia and Herzegovina	Market Surveillance Agency (MSA BiH)
Brazil	National Institute of Metrology, Quality and Technology (Inmetro)
Canada	Health Canada
Colombia	Superintendencia de Industria y Comercio (SIC)
Czech Republic	Czech Trade Inspection Authority
Denmark	Danish Safety Technology Authority
European Union	European Commission (EC)
Finland	Finnish Safety and Chemicals Agency (Tukes)
France	Direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF)
Germany	Bavarian State Ministry of the Environment and Consumer Protection
Israel	Standardization Administration Ministry of Economy
Japan	Ministry of Economy, Trade and Industry
Netherlands	Food and Consumer Product Safety Authority (NVWA)
New Zealand	Trading Standards
Russian Federation	Federal Service for Surveillance on Consumer Rights Protection and Human Well-being (Rospotrebnadzor)
Singapore	SPRING
Slovakia	Slovak Trade Inspection
Slovenia	Market Inspectorate of the Republic of Slovenia
Turkey	Ministry of Economy DG for Product Safety and Inspection
United States	Consumer Product Safety Commission (CPSC)

Consultations

On 21 August 2015, Health Canada circulated the report to the WP and survey participants for input. This offered an opportunity for participating jurisdictions to provide any clarifications or additional detailed information to supplement their originally supplied responses. All feedback was then gathered and incorporated into the present report.

² PROSAFE is a non-profit professional organisation for market surveillance authorities and officers from throughout the European Economic Area (EEA). It co-ordinates joint market surveillance activities that are financially supported by the European Commission.

Considerations

Terms used in the survey

It was quite difficult to avoid using risk-related terms in the survey which may have specific meanings in different jurisdictions. To help facilitate a common understanding of the concepts and terms used, some explanations were provided throughout the survey, along with many examples of the kinds of uses of risk assessment that were being examined. Jurisdictions were also asked to provide key definitions used in their risk assessment processes; these are compiled in Annex B to this report.

Summarising of responses and examples

In summarising the survey responses, certain details specific to particular jurisdictions were highlighted as examples. These detailed examples may also hold true to other jurisdictions, however, such similarities may not have been acknowledged in all cases.

Different authorities and product responsibilities

The findings of the survey have been examined keeping in mind that authorities may have different regulatory mandates, including differences in regulated products and entities. The definition of what constitutes a “consumer product”, for example, may vary widely among jurisdictions. In addition, some authorities may also be responsible for other product types outside the scope of what they might define as consumer products (e.g. cosmetics, medical devices, drugs, or automobile products).

Summary of Survey Results: Risk Assessment and Risk Management

This section describes the survey participants’ responses to questions with respect to how they define risk assessment and risk management, how they structure their own processes, what tools they use and what factors they take into account in their risk assessment work.

Risk assessment and risk management are two key concepts in product safety. *Risk assessment* is a systematic process for evaluating the potential risk posed by a product in order to inform decision-making. *Risk management* is a term used to collectively describe the activities and considerations involved in addressing and communicating information about risks under conditions of uncertainty. Risk management generally includes a number of inter-related activities such as: risk identification, risk assessment, risk mitigation and risk communication. Box 1 illustrates Health Canada’s approach to risk assessment and management.

Box 1. Health Canada’s Risk Assessment Framework

Health Canada’s Consumer Product Safety Program defines risk assessment and other important risk assessment terms and concepts in its Risk Assessment Framework. The Program keeps risk assessment determinations and decisions on risk management actions separate. Risk assessments are conducted by risk assessors who make a determination with respect to the risk level associated with a product. These conclusions are then used by risk managers within the Program to determine what, if any, risk measure is needed. Risk measures take into consideration factors such as public perception, availability of the product, political pressures, etc. Such factors may be part of the “risk assessment” in other jurisdictions.

Definition of risk assessment

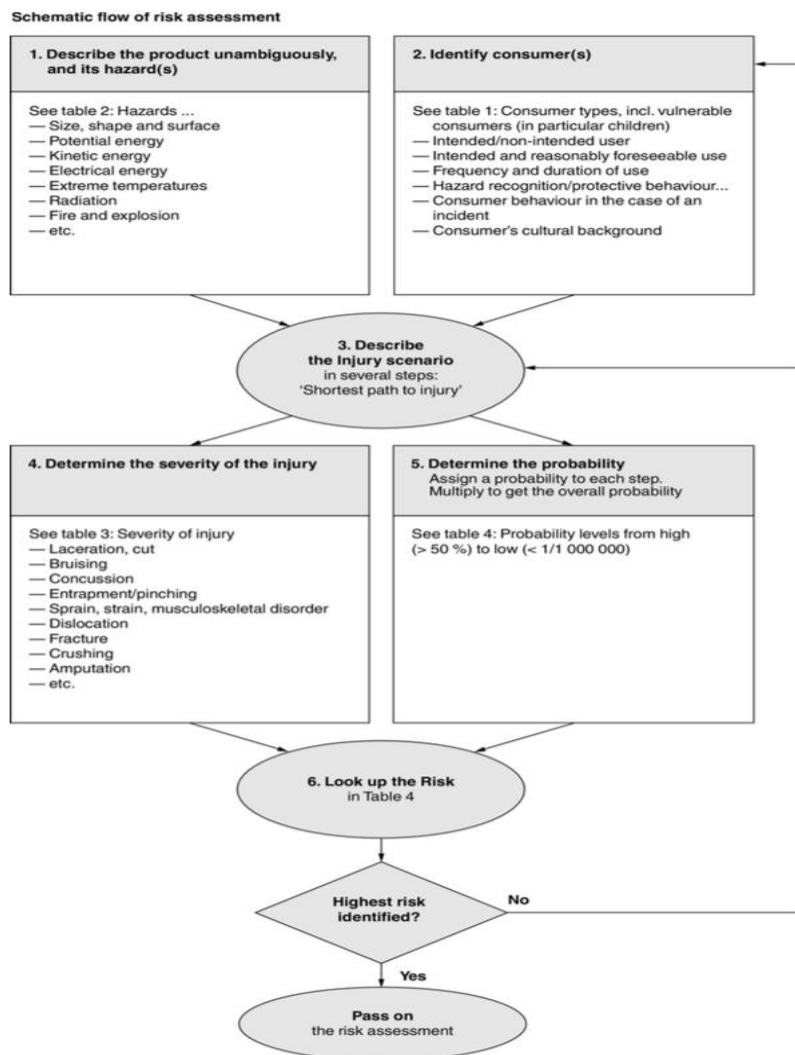
All EU Member States, Bosnia and Herzegovina and Turkey, reported using the risk assessment definition laid down in the risk assessment guidelines for consumer products (the EU Alert Guidelines) of the European Rapid Alert System (RAPEX) risk assessment guidelines for consumer products (hereafter "EU Alert Guidelines") (Box 2). A schematic flow of risk assessment resulting from such guidelines is provided in Figure 1.

Box 2. Definition of risk assessment in the EU Alert Guidelines

Risk assessment: Procedure for identifying and assessing hazards, consisting of three steps:

- Identification of the seriousness of a hazard;
- Determination of the probability that a consumer will be injured by that hazard;
- Combination of the hazard with the probability.

Figure 1. Schematic Flow of risk assessment from the EU Alert Guidelines



Source: Official Journal of the EU: Legislation: Volume 53, 26 January 2010, Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX'.

Russia has a reference to risk assessment in its legislation with a legal framework that defines “harm” as not only covering physical injury but also other kinds of health deterioration. Brazil made reference to the definition provided by the International Organization for Standardization (ISO) included in Table 2. Canada, Colombia, Japan, New Zealand and Singapore all reported having definitions laid down in their own operating procedures. Only Israel reported not having any definition for risk assessment laid down in legislation or internal procedures. The definitions provided in the survey responses all referred to a definition of risk assessment similar to that of ISO 10377.

Table 2. ISO 10377 (ISO/IEC Guide 51) – Selected terms and definitions³

Term	Definition
Risk assessment	Overall process comprising a risk analysis and a risk evaluation
Risk analysis	Systematic use of available information to identify hazards and to estimate the risk
Risk evaluation	Procedure based on the risk analysis to determine whether the tolerable risk has been achieved
Tolerable risk (acceptable risk)	Risk which is acceptable for a specific user group based on the current values of society
Hazard	Potential source of harm
Harm	Physical injury or damage to the health of people, or damage to property
Risk	Combination of the probability of occurrence of harm and the severity of that harm

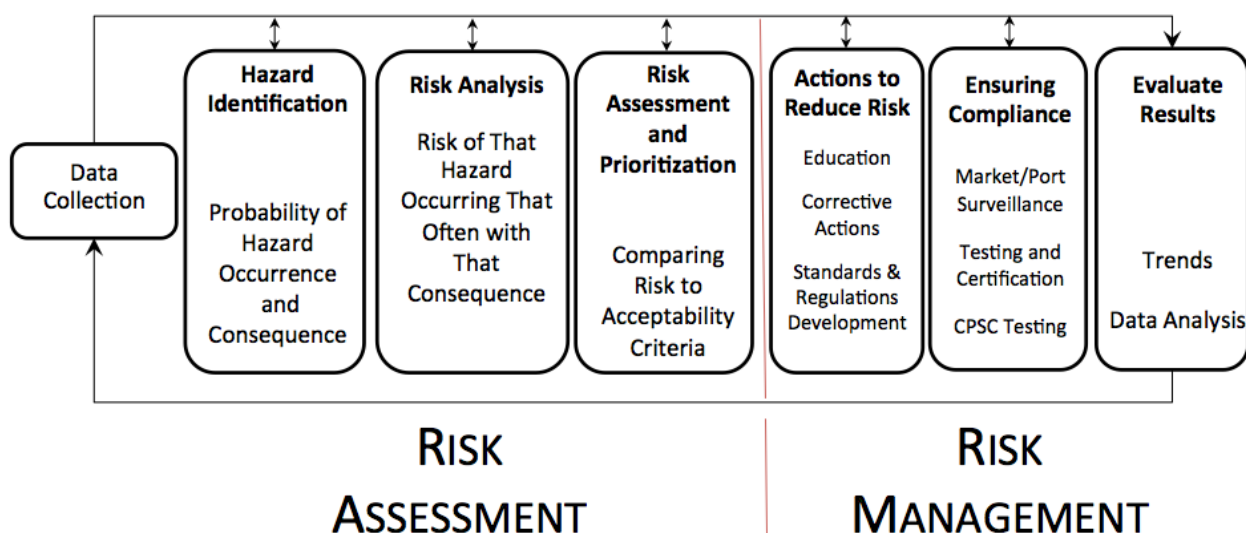
Definition of risk management

All EU Member States, Bosnia and Herzegovina and Turkey, noted that risk management is defined in the EU Alert Guidelines as “follow-up action, which is separate from risk assessment and aims to reduce or eliminate a risk”. Russia and Israel also have references to risk management in their legislation. Japan defines risk management in its guidance to manufacturers and importers, while Brazil cited an ISO standard. New Zealand and Colombia noted that a risk management approach was not defined directly in their legislation but the use of such an approach could be inferred through their legislative frameworks and operating procedures. The definitions provided were consistent with that contained in the EU Alert Guidelines.

Separation of risk assessment and risk management processes

Jurisdictions were asked if their risk assessment and risk management processes were separate, such as through policies or procedures or through implementation by different parts of the organisation. Although few details were provided, the responses indicated that the processes were separated, with the exception of Israel at this time. A diagram of the US CPSC risk management process is presented in Figure 2.

³ ISO 10377:2013 Consumer product safety -- Guidelines for suppliers, available at: www.iso.org/iso/catalogue_detail.htm?csnumber=45967.

Figure 2. US CPSC Risk Management Process⁴

Factors informing risk assessment processes

Jurisdictions were asked to identify the factors they take into account when assessing risks. A list of factors identified during the 2013 OECD Risk Assessment Workshop (Table 3) reflects those used by the vast majority of the jurisdictions.

Table 3. Summary of responses indicating use of specific factors

Factor	Yes	No
The way the product is used	20	0
How widespread the use of product is	17	3
Whether the product is new	10	10
The accessibility of the product once purchased	17	3
The level of perceived risk by consumers	16	4
Whether the product could impact a vulnerable consumer group	19	1
Is it attractive to a specific risk group?	19	1
Are there multiple types of potential exposure to consider? And related levels of toxicity?	18	2
Whether the instructions and warnings are clear	17	3
Injury scenarios	20	0
The severity of injury and potential health effects	20	0
Probability of harm occurring	20	0

The following summarises additional information provided by some jurisdictions on some of the above factors with respect to their own operations.

⁴ US CPSC. *CPSC's Risk Assessment of Electrical Products in a Global Environment*, Submission of the United States to the APEC Workshop on Developing a Harmonised Electrical Equipment Regulatory Risk Assessment Tool held in Singapore on 15-16 May 2012, at: http://mddb.apec.org/documents/2012/SCSC/WKSP1/12_scsc_wksp1_010.pdf.

How widespread use of the product is

The European Commission noted that the widespread use of the product is indirectly taken into account in the EU Alert Guidelines as part of the probability scenario in the risk assessment process. Canada reported that the core of the risk assessment does not take into account how widespread a product is, as this is seen as a risk management consideration. However, Canada has developed a risk characterisation methodology for consumer products that identifies both user and population risk. In determining the population risk, the methodology accounts for the level of product usage among the population being studied. The population risk is an outcome of the risk assessment, viewed as a tool that can be used by risk managers to determine priorities and to undertake an analysis of what risk measures may be most appropriate.

Whether the product is new

Brazil noted that risk assessment is used to help determine the need for regulatory activity and that the scope of new regulations was restricted to new products. The issue of dealing with the life cycle of consumer products is currently being studied in Brazil in addition to how it should be addressed. This survey question was perhaps a little ambiguous as in fact it was meant to refer to second-hand products. This issue has, for example, been raised in the Consumer Policy Committee of the International Organization for Standardization (ISO-COPOLCO); the re-sale market in children's products (particularly recalled products) is a concern for many regulators. The question of the life cycle of products such as some large household appliances is being addressed in Japan.

The accessibility of the product once purchased

The European Commission noted that the accessibility of the product once purchased is indirectly taken into account in the EU Alert Guidelines in the probability scenario during the risk assessment. France also noted that, in the context of accident scenarios used in the risk assessment of the product, the authority takes into account aspects related to the product itself (e.g. intrinsic danger, safety of the packaging, sufficiency of warnings, potential to be misused or user groups to which the product is not intended etc.), how it will be stored, as well as the frequency of use of the product.

The level of perceived risk by consumers

Canada indicated that they did not directly take into account consumer risk perception since this factor is not anticipated to impact the overall risk level. However, this consideration could be taken into account by risk managers when determining whether risk measures are needed, such as information to provide to consumers on the risks.

Other factors not listed above

Jurisdictions were also given an opportunity to identify other factors not listed above. Colombia identified the likelihood of product acquisition due to price; whether the product is marketed to the public in general or to a specific consumer group; and incorrect information about instructions or warnings such as selling a toy that is not a toy and concealing information. Denmark noted that the supervision of vulnerable population users could influence the risk assessment; protective equipment being used or present might also have influence. Finland cited case-specific factors that may come up during the market surveillance procedures. France takes into account the number of products that have been placed on the market. Israel considers the module of product release from Customs and the history of the importing or the manufacturing company. Japan also considers a number of additional factors. These include the composition of the product; how the product will be used along with other products (are there any optional accessories?); how the product will be distributed, kept in storage and assembled; how the product will be

sold to a customer (face-to-face or online?); and how the product will be discarded after the end of its life (are there any harmful materials or residual energy?).

In the injury scenarios⁵ developed by the Dutch authority consistent with the EU Alert Guidelines, not only the intended or foreseeable user is taken into account, but also the possible injury of bystanders not directly interacting with the product. The situation in which the product is used can also be important (e.g. barbecues being used indoors or electrical equipment in bathroom). An example of other factors taken into account in risk assessment in Canada is presented below in Box 3.

⁵ An injury scenario describes the accident that the consumer has with the product in question and the severity of the consumer's injury caused by that accident. Several injury scenarios leading to several risks can be developed for virtually every product.

Box 3. Other factors taken into account in risk assessment in Canada

- Test results:
 - Health Canada has a Product Safety Laboratory that conducts testing to inform risk assessment and risk management;
 - Test results from suppliers or other sources also may be used to inform risk assessment and risk management.
- The severity of the potential injury or near-miss;
- The number or pattern of reports related to the particular product or product type in question;
- A determination of whether the hazard is present when the product in question is used or misused in a reasonably foreseeable manner;
- The user(s) for whom exposure is being estimated;
- The specific use of, or exposure to, the product and likely user behavior;
- The phases of product use;
- Product preparation (e.g. assembly by a consumer);
- Direct use;
- Post-use;
- Disassembly or removal;
- The usual circumstances or environment(s) in which the use takes place (indoor/outdoor, consumer versus occupational, poorly ventilated versus well-ventilated areas, etc.);
- The hazardous property under consideration (flammability, sharpness, toxicity, etc.) and the chemical/physical characteristics of substances within the product that may influence their exposure (volatility, bio-accessibility, bioavailability, etc.). This includes aspects of the product, such as ingredients or concealed parts, which may/may not be accessible to users;
- How obvious or detectable the hazard is;
- The route of exposure (oral, dermal, inhalation, etc.);
- The duration and frequency of use and exposure;
- The product lifespan and wear.

Factors informing the risk management process

Jurisdictions were asked to point to the factors taken into account when selecting and implementing options to manage risks. In some instances, identical or similar considerations were reportedly taken into account during both the risk assessment and risk management processes.

EU Member States referred to chapter four of the EU Alert Guidelines, which deals with factors involved from risk to action (i.e. *i*) accumulation of several less than serious risks, *ii*) overall population exposure, *iii*) probability of fatal accidents, and *iv*) other risk-related aspects such as cultural or political sensitivities or vulnerability of the end consumers). Some EU Member States also specifically mentioned factors that they would take into account when deciding to take action such as any voluntary action undertaken by the economic operator and the market size (exposure level of the population).

France noted that in addition to the level of risk as defined by the risk assessment procedure, the identity and number of economic operators responsible for the distribution of the product in question would be considered when managing risks. The assessment of the capacity of economic operators to manage the risk situation would involve looking at their prior history, their internal organisation, whether they had product recall procedures in place and any product traceability device to the effective downstream means available, as well as the previous management of such crises. France's assessment of a risk management approach by an economic operator (involved in a situation and in control over the actions) would include the resources used, media coverage options chosen, intensity and effectiveness of the communication to the consumers concerned and monitoring the rate of recovered products.

Colombia described its risk management process as consisting of a number of steps. First, products that could eventually threaten the life or safety of consumers are selected. For this selection, the SIC takes into account the presence of the product on the market, the consumer vulnerability, risk level, the severity of the possible injury, and reported accidents. A risk assessment is then conducted for that particular product, followed by an assessment of decisions to adopt in order to mitigate risk. Criteria have been established between the results of risk assessment and the measures aimed at mitigating the product hazards to ensure the proportionality of such action. Social and economic aspects are also taken into account.

New Zealand uses a nomograph⁶ as the initial means of analysis that is followed up with direct contact with key stakeholders and noted experts. Depending on the issue, New Zealand makes direct contact with the National Children's Hospital (Starship in Auckland), child care and safety organisations (Safekids, Plunket), other regulators (for example to tap into toxicological expertise etc.), and business sector representatives. The views and guidance New Zealand received help shape their response. While most of these interactions are informal, some memoranda of understanding are in place; work is also underway across the government looking at how and when information and intelligence is shared and also developing joint work on sector/specific issues.

Japan is concerned whether a certain risk is tolerable enough to be accepted in a given context based on the current values of society (the level and the magnitude of a hazard of a certain risk). Singapore takes into account a broad range of factors such as business cost, one-off or wide spread incident, past records, design fault/misuse, and international trends/practices. The United States identified their concern with feasibility, utilisation, effectiveness (how much risk is reduced), efficiency (relation of benefits to costs), and equity (distribution of who benefits and who incurs burden). Canada included a number of additional factors that are taken into account during the risk management process (listed in Box 4).

⁶ A nomograph is a two-dimensional diagram designed to allow the approximate graphical computation of a function. When applied to risk assessment, the nomograph plots the risk as the relationship between the severity of an injury and the probability of a hazard occurring.

Box 4. Example of factors taken into account in the risk management process in Canada

- Results of the risk assessment;
- Seriousness/Imminence of the risk to human health or safety;
- Obviousness of the danger and normal public expectations of the product's safety;
- Availability of economically feasible alternatives (i.e., safer designs, alternative products);
- Ability of consumers to mitigate the risks themselves;
- Whether the product complies with an available health and/or safety standard, a regulation, or published guidelines from Health Canada or another relevant organisation (e.g. regulators in other jurisdictions, industry associations, etc.);
- International processes, agreements or obligations;
- Corporate and internal governance;
- Industry-related factors such as history of compliance;
- Availability or frequency of use of a particular product;
- Impact on vulnerable populations;
- How quickly the issue must be addressed, including the consequences of delaying action;
- Magnitude of the hazard;
- Economic and social utility of a product; and
- Any other relevant factors specific to the case.

Written procedures or guidance documents for risk assessment and risk management

All jurisdictions, with the exception of Israel, reported having written procedures or guidance material. European countries cited the EU alert guidelines and other European guidance documents. Where possible, the documents identified in the responses and other relevant documents have been collected and uploaded to the regulators-only portion of the OECD WP website.

Canada adopted an overarching Risk Assessment Framework⁷ in 2014, and is currently developing a Risk Management Framework. The Risk Assessment Framework provides information, clarity and transparency to stakeholders on Health Canada's approach to risk assessment in its Consumer Product Safety Program and related guiding principles. The framework establishes a foundation for the way the Program considers health or safety risks and outlines its risk assessment process. In addition, Health Canada has standard operation procedures, policies and guidance documents for many aspects of their work for risk assessment and risk management. For example, with respect to risk management, Canada has a compliance and enforcement policy that contains policies and standard operating procedures related to compliance and enforcement activities such as: processing of incident reports related to compliance and enforcement, inspections, sampling, cyclical enforcement, import surveillance, guidance on the appropriate response to non-compliance, and the implementation of the selected compliance and enforcement actions.

7

See: www.hc-sc.gc.ca/cps-spc/legislation/pol/risk-framework-cadre-risques-eng.php.

Some of the material⁸ identified by the participants was aimed at manufacturers and importers. Such material, for example, included the Japanese handbooks about risk assessment developed mainly for manufacturers and importers in 2010 and 2011; it also included similar guidance material from the United States that has also been translated into Chinese.

Use of specific risk assessment tools

For the purposes of this survey, a tool can be defined as any checklist, form, table, algorithm, application/program or resource that assists your organisation in making a determination of risk. A variety of different risk assessment tools were identified by survey participants, including:

- Risk Assessment Guidelines (RAG) online tool (EU Member States, Bosnia and Herzegovina, Turkey, Brazil, Colombia);
- Risk Matrix (Japan);
- Nomograph (Australia, New Zealand, Singapore);
- Fault tree/event tree analysis (United States);
- Risk Assessment Methodology (RAM) (United States);
- Bow-tie analysis (Brazil);
- Triage Tool (Canada).

Russia and Colombia reported additional systems; Israel reported not having currently any formal guidelines.

Risk Assessment Guidelines (Rag) Tool

The RAG tool is an online application provided by the European Commission to perform risk assessments according to the EU Alert Guidelines. The tool comprises all elements necessary for market surveillance authorities to carry out a risk assessment of a non-food product: identification of a product group, hazard group, type of consumers, injury scenario, severity of injuries, determination of probabilities and determination of risk level of product. An example of the risk assessment template in the RAG online tool is included in Figure 3.

Some EU Member States have developed their own additional guidance and tools to complement the RAG tool. France has developed instructions and a specific evaluation grid that is used to assess the risk level of economic operators covered by the preventive control procedure of the first directors on the French market, contrôles de première mise sur le marché (CPMM) (Initial Market Release Control).

⁸ The handbooks are available at: www.meti.go.jp/product_safety/recall/risk_assessment.html (Japanese language only).

Figure 3. Example of a risk assessment template in the EU RAG online tool

Risk Assessment for RAPEX

General Information and Overview

Product Product name <input type="text"/> Product category <input type="text"/> Description <input type="text"/>	Risk assessor First name <input type="text"/> Last name <input type="text"/> Organisation <input type="text"/> Address <input type="text"/>
----------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------

Product risks - Overview
Overall risk

Scenario summary

Scenarios Expand All / Collapse All

Scenario 1 ▲ 🗑

Product hazard Hazard group <input type="text"/> Hazard <input type="text"/>	Consumer type <input type="text"/>		
How the hazard causes an injury to the consumer Typical injury scenario <input type="text"/> <input type="button" value="Copy >"/> Your injury scenario: Describe it! <input type="text"/>			
Severity of injury Typical injury <input type="text"/>	Your injury <input type="text"/> Select below a severity level (1 to 4) 1 _____ 2 _____ 3 _____ 4 _____		
Probability of injury Step(s) to injury: Describe - 1 step per box <input type="text"/> <input type="button" value="Add a step"/>	Probability: Enter a value between 0.000001 and 1. <input type="text"/> <input type="button" value="🗑"/>		
Severity of injury level	Calculated probability	Overall probability	Risk of this scenario

Source: Official website of the European Union:

<http://europa.eu/sanco/rag/public/index.cfm?event=home&CFID=200306&CFTOKEN=33804628&jsessionId=08a3716979f23bbfe8f13c6d3c6a31537ed1TR>.

Risk Matrix (R-Map)

Japan has developed the “R-Map” (Risk-Map) method in order to visualise whether i) a certain risk is tolerable enough to be accepted in a given context based on the current values of society and ii) a protection measure is effective enough to mitigate the risk. In this method, Japan uses a matrix with the occurrence frequency of a hazard as a vertical axis and the magnitude of a hazard as a horizontal axis. The tolerance of the risk is evaluated using the method, as illustrated in Figure 4.

Figure 4. Calculation of risk tolerance under Japanese R-map method

Occurrence Frequency	5	frequently	C	B3	A1	A2	A3	Area A
	4	occasionally	C	B2	B3	A1	A2	
	3	sporadically	C	B1	B2	B3	A1	
	2	rarely	C	C	B1	B2	B3	Area B
	1	very little	C	C	C	B1	B2	Area C
	0	hardly	C	C	C	C	C	
		no hurt	mild	critical	serious	fatal		
		0	I	II	III	IV		

Area A is the intolerable risk area. If this risk happens during the product development stage, countermeasures should be taken immediately. If there is risk which cannot be reduced then the product should not be developed any further. If the product has already been released into the marketplace, it should be publicly recalled (and repaired).


Area B is the ‘As Low as Reasonably Practicable’ (ALARP) area. Products developed and produced in this area must not have any risk, except where the technology has beneficial side-effects. The ALARP principle is that the residual risk shall be as low as reasonably practicable; only if risk reduction is not feasible or the cost involved in reducing the risk is disproportionate to the benefit gained, will the risk be tolerable.

Area C is the safety area. In this area, compared with other tolerable risks, there is relatively low risk of harm and frequency. In this area risk can be ignored.

Source: Q grow: Risk management and the R-map, Matsumoto Koji, Products Safety Advisor in Products Safety Technology Centre, Japan.

The R-Map approach to evaluating risk is essentially the same as the one adopted in the EU RAPEX Guidelines, as is illustrated in Figure 5.

Figure 5. . Risk level from the combination of the severity of injury and probability (EU alert guidelines)

Probability of damage during the foreseeable lifetime of the product		Severity of injury			
		1	2	3	4
High  Low	> 50 %	H	S	S	S
	> 1/10	M	S	S	S
	> 1/100	M	S	S	S
	> 1/1 000	L	H	S	S
	> 1/10 000	L	M	H	S
	> 1/100 000	L	L	M	H
	> 1/1 000 000	L	L	L	M
	< 1/1 000 000	L	L	L	L

S — Serious Risk
H — High risk
M — Medium risk
L — Low risk

Source: Official Journal of the EU: Legislation: Volume 53, 26 January 2010, Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX'.

Nomograph

Australia, New Zealand and Singapore use a nomograph method. Singapore also uses the Association of Southeast Asian Nations Electrical and Electronic Equipment (ASEAN-EEE) risk assessment guidelines, which cover with electrical and electronic equipment and provide definitions for some hazards and for injury severity. An example of a nomograph is provided in Figure 6.

Figure 6. Example of Nomograph

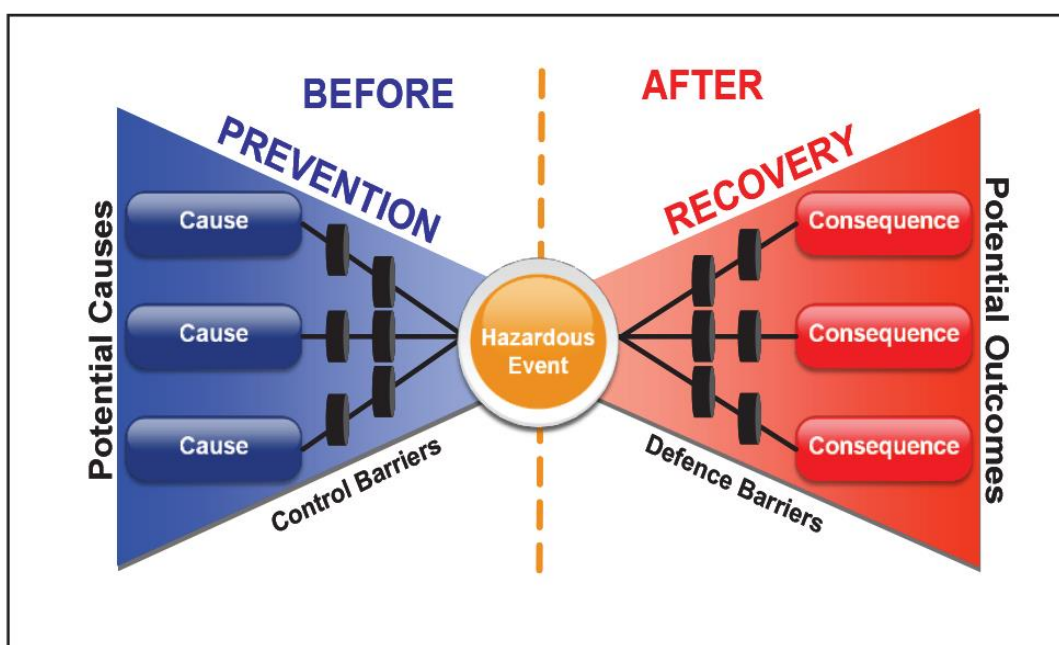


Source: ACCC Product Safety Nomograph Tool: Australia PS - ACCC Product Safety Nomograph Tool and Instructions for Use (4).

Bow-Tie Analysis

Brazil stated that as part of its Compliance Assistance Process, it uses the bowtie diagram as a tool for identifying and proposing treatments (barriers) for the operational risks from the regulatory process (i.e. those risks related to the regulation compliance or delivery). Operational risks from the regulatory process are different from risks that apply to products. They have a different level of complexity and deal with a huge number of sources of risk. As a diagram, the bowtie gives a better visual presentation of this complexity. The graphic focuses on the barriers (treatments) that should be used to treat/mitigate risks. The right side of the bowtie diagram also reveals the impacts that may occur when risks are not treated and mitigated and what should be done as a result (barriers from the right side). An example of a bow-tie diagram is provided in Figure 7.

Figure 7. Bow Tie Diagram



Source: ERM, <http://events.r20.constantcontact.com/register/event?llr=6quxcycab&oeidk=a07e5zzlwto9ff6b679>.

The US CPSC uses a variety of tools, including Risk Assessment Methodology (RAM - see Box 8 below) and tools for prioritising product hazards for standards development and tools such as event trees, fault trees and failure modes and effects analyses that are used in individual projects. Event tree analysis (ETA) is a logical evaluative process which works by tracing forward in time or forwards through a causal chain to model risk. It does not require the premise of a known hazard. An event tree is an inductive investigatory process. In contrast, the Fault Tree Analysis (FTA) evaluates risk by tracing backwards in time or backwards through a cause chain. The analysis takes as a premise a given hazard; it is a deductive investigatory process (see Figure 8).

Another tool used by the US CPSC is Failure mode and effects analysis (FMEA). This is a systematic technique for failure analysis (Figure 9). It involves reviewing as many components, assemblies, and subsystems as possible to identify failure modes, and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet. There are numerous variations of such worksheets. FMEA is mainly a qualitative analysis.

Figure 8. Failure Tracing Methods⁹

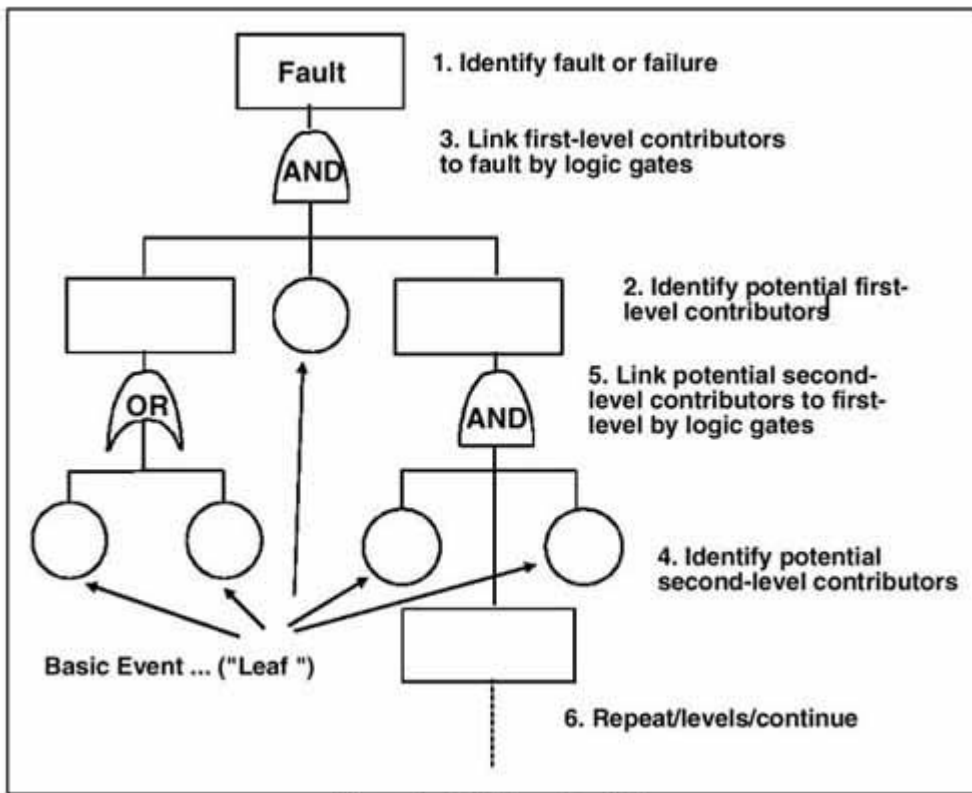


Figure 1. Fault Tree Analysis

Figure 9. ¹⁰. Example of FMEA Form¹¹

FMEA Process										
Component & Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Controls	Detection	RPN	Recomm'd Action	Response & Target Completion Date

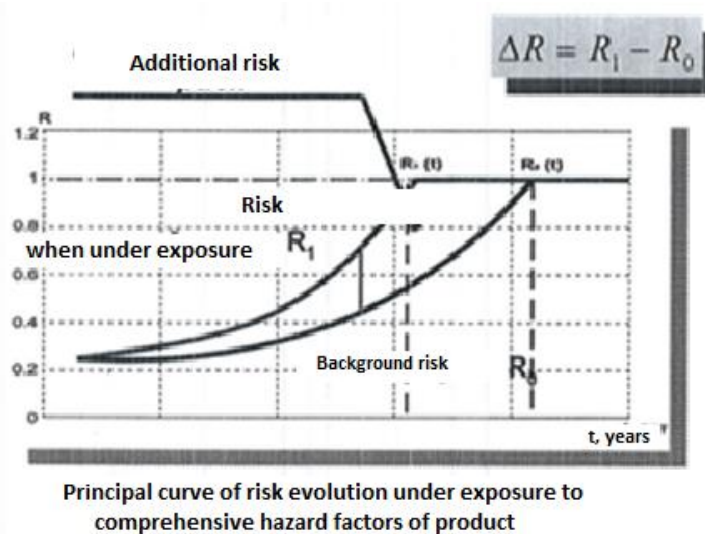
Russia conducts their risk assessment procedures based on the application of risk evolution modeling, which, in addition to methods recommended by international organisations, allows risk assessment of the product to be conducted with comprehensive hazard factors of different natures (chemical, biological, and physical). It also takes into consideration risk evolution (accumulation) for long-term usage of the product, as well as age-related characteristics of the customers (Figure 10).

⁹ See: NASA, at: <http://lis.nasa.gov/lesson/757>.

¹⁰ RPN stands for risk priority number and is calculated as a product of occurrence, severity and detectability.

¹¹ See: www.qualitytrainingportal.com/resources/fmea/form_46a_app12amod.htm.

Figure 10. Risk Evolution Graph



Source: Graph provided by Rospotrebnadzor on 10 September 2015.

Triage Tools

Industry and consumer reports to Health Canada and emerging trends are subject to an initial triage and prioritisation process to determine the urgency of response and whether further risk assessment activity is necessary. The priority of an issue and the resources dedicated to its further assessment can be adjusted if they prove to be more or less serious than originally estimated.

A number of factors influence the initial triage and prioritisation process which provides a preliminary indication of the level of potential risk to human health or safety to the Canadian public. These factors include:

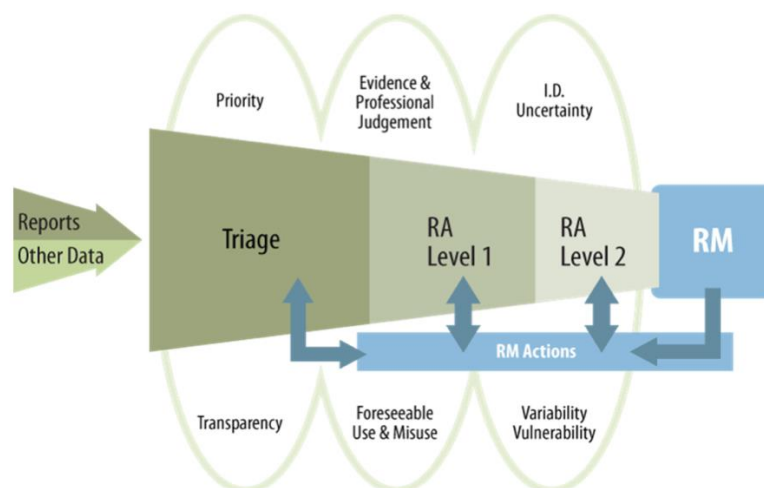
- The severity of the actual or potential injury or near-miss or death;
- The age of the person affected (e.g. children or seniors);
- The extent of wear and age of the product in question;
- The number or pattern of reports related to the particular product or product type in question; and,
- A determination of whether the hazard is present when the product in question is used or misused in a reasonably foreseeable manner.

Reports or emerging trends involving specific vulnerable populations will receive higher priority. Generally, of these, young children will receive the greatest weight for this factor in the priority setting tool. Other vulnerable sub-populations, such as seniors, will also receive a higher weight than a healthy middle aged adult. Priority setting for a risk assessment may also be informed by human health or safety risks identified by another authority within or outside of Canada. In those cases where further assessment activity is determined not to be necessary or a priority, surveillance experts may continue to monitor media, other international consumer product regulators, health and safety organisations and other sources

for any further activities or information that may inform or identify the need to revisit or take further assessment activity on a given case.

Figure 11 shows where the triage tool sits within Health Canada's Risk Assessment process.

Figure 11. Health Canada Risk Assessment Framework



Source: Canada Consumer Product Safety Program's Risk Assessment Framework presentation: Risk Assessment Survey, provided at the WP's risk assessment virtual symposium held on 2 April 2015.

Risk Assessment Systems

The following sections explore the use of different systems for assessing risks.

Systems to classify or code hazards

The EU Alert Guidelines identify a broad range of hazard groups (Table 4). In respect of each group, a number of hazards (product properties) are identified. Typical injury scenarios and injuries are then described for each one. This coding is also used by EU candidate countries such as Bosnia and Herzegovina, Turkey, Brazil and Colombia. Canada, Japan, Russia and the United States have developed their own coding systems. Israel, Singapore and New Zealand did not report having any formal systems of their own in place.

Table 4. Hazard Groups identified in the EU Alert Guidelines

Size, shape and surface	Kinetic Energy	Extreme Temperatures	Fire and Explosion	Microbiological contamination
Potential Energy	Electrical Energy	Radiation	Toxicity	Product Operating Hazards

For risks associated with the products, France uses the classification according to the 4 levels of the EU Alert Guidelines. For risks associated with economic operators, France uses 3 levels: low, medium and high.

Systems to grade or code the severity of injuries

The EU Alert Guidelines also contains exhaustive advice concerning the severity of different types of injury. All EU Member States, Bosnia and Herzegovina, Turkey, Brazil and Colombia reported using these guidelines. A number of jurisdictions, including Canada, Japan, Russia and the United States, identified their own systems to grade or code the severity of injuries. The Canadian injury coding manual categorizes the severity of injuries or potential injuries. The coding manual includes tables, which list injury type (e.g. fractures, burns, electric shock, poisoning) as well as injury severity by injury type. Singapore reported using guidelines from New Zealand that had been developed for gas appliances and electrical appliances¹². Only Israel and New Zealand reported that they did not have any formal systems in place. Table 5 and 6 below provide examples of, respectively, the injury coding used in the EU Alert Guidelines and the Japanese R-map method.

¹² Source: New Zealand Ministry of Consumer Affairs (Energy Safety), A Risk Assessment System for Gas and Electrical Appliances & Installations.

Table 5. Classification of injury in the EU Alert Guidelines

Type of injury	Severity of injury			
	1	2	3	4
Laceration, cut	Superficial	External (deep) (> 10 cm long on body) (> 5 cm long on face) requiring stitches Tendon or into joint White of eye or cornea	Optic nerve Neck artery Trachea Internal organs	Bronchial tube Oesophagus Aorta Spinal cord (low) Deep laceration of internal organs Severed high spinal cord Brain (severe lesion/dysfunction)
Bruising (abrasion/contusion, swelling, oedema)	Superficial $\leq 25 \text{ cm}^2$ on face $\leq 50 \text{ cm}^2$ on body	Major $> 25 \text{ cm}^2$ on face $> 50 \text{ cm}^2$ on body	Trachea Internal organs (minor) Heart Brain Lung, with blood or air in chest	Brain stem Spinal cord causing paralysis
Concussion	—	Very short unconsciousness (minutes)	Prolonged unconsciousness	Coma

Table 6. Classification of injury under the Japanese R-map method

	Qualitative expression	Hazard against human	Fire
iv	Catastrophic	Death	Fire, burnout of the building
iii	Critical	Serious injury or need to be hospitalized	Fire
ii	Marginal	need to be get outpatient treatment	Fire from the product, burnout of the product
i	Negligible	Slight injury	Smoke from the product
0	None	None	None

Comparability of the different systems

Where different systems for injury coding exist, the question about how compatible such systems are arises. An evaluation¹³ has been made of the comparability between two injury coding systems, the US CPSC National Electronic Injury Surveillance System (NEISS) and the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). Results showed that there was potential for conducting comparable injury research using NEISS and ICD-9-CM data. The issue was discussed during the 2013 OECD workshop on risk assessment where it was pointed out that while there are many similarities between systems, there are instances where the systems will accord a different level of severity to a specific injury. This is due to the threshold applied by each system is slightly different. As a result, the same injury may trigger an investigation in one jurisdiction but not in another.

Probability Factors

Some of the risk assessment processes described by respondents also included systems for probability factors. Two examples of such systems, including the Japanese R-map method and the EU Alert Guidelines are provided in, respectively, Table 7 and Figure 12.

Table 7. How probability is addressed in the Japanese R-Map method

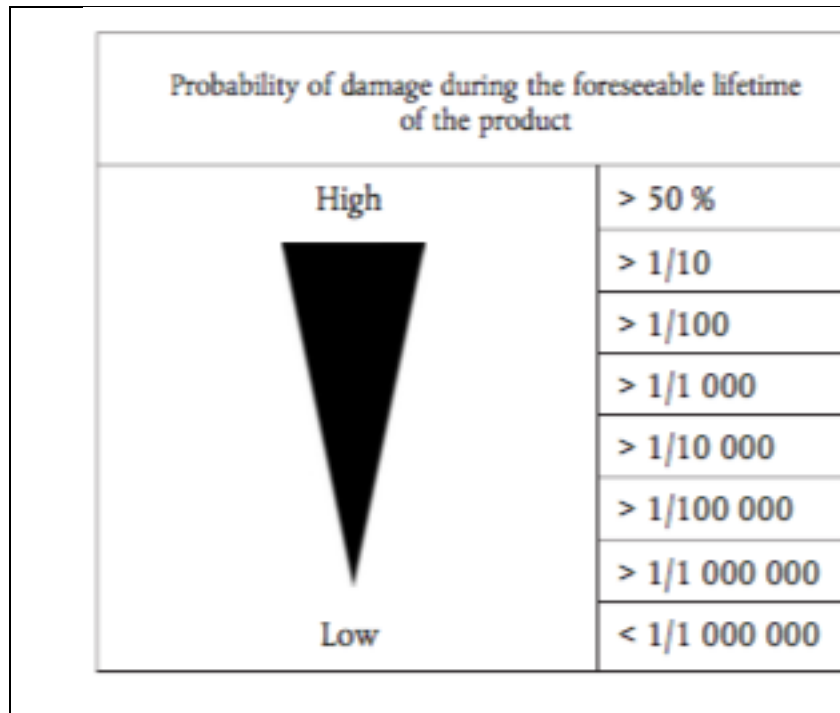
Classification of the occurrence frequency of a hazard in R-Map Method Japan				
The occurrence frequency				
Level	Qualitative expression	Quantitative expression(incident/unit/year)		
5	Frequent	more than 10^{-2}	more than 10^{-3}	more than 10^{-4}
4	Probable	$10^{-3} \sim 10^{-2}$	$10^{-4} \sim 10^{-3}$	$10^{-5} \sim 10^{-4}$
3	Occasional	$10^{-4} \sim 10^{-3}$	$10^{-5} \sim 10^{-4}$	$10^{-6} \sim 10^{-5}$
2	Remote	$10^{-5} \sim 10^{-4}$	$10^{-6} \sim 10^{-5}$	$10^{-7} \sim 10^{-6}$
1	Improbable	$10^{-6} \sim 10^{-5}$	$10^{-7} \sim 10^{-6}$	$10^{-8} \sim 10^{-7}$
0	Incredible	less than 10^{-6}	less than 10^{-7}	less than 10^{-8}

Example of how to set level 0;
 less than 10^{-7} : Electric wheeled chair, Electric-motor-assisted bicycle.
 less than 10^{-8} : Home electronics, gas equipment, business equipment and other consumer products.

¹³

See: www.ncbi.nlm.nih.gov/pmc/articles/PMC3962381/.

Figure 12. How probability is addressed in the EU alert guidelines



Source: Official Journal of the EU: Legislation: Volume 53, 26 January 2010, Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX'.

Definitions or defined terms used in the risk assessment process

Jurisdictions were asked to point to the definitions used in their risk assessment process. These are included in Annex B to this report.

Assessment of Risks at Different Stages of the Product Safety Framework

Stage One – Legislating, regulating and setting standards

Many jurisdictions have some form of general safety requirement for consumer products. Within those systems, many also include product-specific regulations or standards. Based on these regulations and standards, some product safety authorities will approach regulated and unregulated products differently when determining how to approach certain aspects of their work. “Regulated products” are those covered by specific regulations. “Unregulated products” would be all those that are not covered by the regulations but would be covered under the general safety requirement (or a general prohibition).

What we learned from the responses to the survey

General safety requirements

Eighteen of the twenty-one jurisdictions reported having a general safety requirement in their legislation. Safety can be generally described as a state (situation) where any unreasonable risk to human life or health (users of product), to property or to other protected values is absent. This general safety requirement appears to be a general trend towards a best practice. The classic example is the definition provided in the EU General Product Safety Directive¹⁴ (GPSD) (Box 5). A general safety requirement has been recently adopted in Canada and implied in New Zealand through the Consumer Guarantees Act. Australia, Brazil and Japan continue to regulate product by product.

Box 5. General safety requirement in the EU GPSD

The GPSD is a broad-based legislative framework of a horizontal nature applicable to any non-food product intended for consumers, or likely to be used by consumers. As many EU Directives, the GPSD is binding as to the result to be achieved, upon each European Union Member State to which it is addressed, but leaves the national authorities the choice of form and methods. The GPSD establishes a general safety requirement for any product placed on the market, requiring that only safe products can be placed on the EU market. In the absence of more specific provisions, within the framework of EU law covering safety of consumer products, all the provisions of the GPSD apply.

Regulations or products standards for specific products

Of the twenty-one regulators surveyed, fourteen reported the ability to set or apply product-specific regulations. Examples of such regulations include electrical equipment (Bosnia and Herzegovina), electrical appliances (Japan, Singapore), and toys (Australia, Canada, and the United States). Similarly, fourteen jurisdictions indicated being able to set or apply product-specific technical standards. In the EU, standards are developed by European standardisation organisations based on formal requests set by the European Commission. Some of these standards are developed specifically to support the EU harmonisation legislation (for toys, electrical equipment, etc.) and for the GPSD. Singapore reported that under the Consumer Protection (Consumer Goods Safety Requirements) Regulations, Category 1 General consumer goods are regulated under relevant ISO standards, International Electro-technical Commission (IEC) standards, and European Standards (EN) or ASTM International standards.

When asked about the regulation of specific products, some of the respondents indicated that they were not the competent authorities for regulation, that other organizations in their respective countries develop regulations. This is often the case where there are separate market surveillance authorities established specifically to carry out compliance and enforcement work. In the cases the regulatory authority rests with the government ministry. In the specific case of the United States, the CPSC has delegated authority from the government to regulate consumer products and also carries out the necessary compliance and enforcement activities. In Europe, harmonisation legislation has been enacted for some products or categories of products in order to ensure that products can freely circulate in the internal market. Where it can be justified, EU Member States can also introduce their own national legislation with respect to specific products.

Brazil is one of the countries that have the ability to regulate specific products, but like most countries, any proposed regulation must meet certain criteria and undergo a regulatory impact analysis.

¹⁴ The GPSD is available at: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/general-product-safety/index_en.htm.

The proposed regulation must avoid duplication and adequately address safety risks that aren't yet covered. Its benefits must outweigh any negative socio-economic impacts. The proposed regulation must also be feasible as far as implementation is concerned, and provide the expected results within a maximum period of ten years.

Differentiation between regulated and unregulated products in market surveillance and enforcement

The split in the responses reflected the extent to which jurisdictions have the authority to act when a product is not the object of specific legislation or standards. For example, France noted that all products are subject to a general obligation of safety and subject to market surveillance. In fact in all EU Member States, the United States and Canada, special requirements are identified in greater detail in the case of products subject to specific regulations.

In Canada, while there is some differentiation, the overall risk assessment approach undertaken for regulated products is similar to that for unregulated products. With respect to "regulated products", Health Canada's Product Safety Program maintains a cyclical enforcement (CE) policy whereby CE projects are planned and implemented using a strategic risk-based approach to monitor and verify industry compliance. Identified compliance issues are addressed with appropriate, uniform, and transparent enforcement activities. Note that the *Canada Consumer Product Safety Act* (CCPSA) also sets out products that are excluded from the Act. With the exception of cosmetics, which are covered under the FDA by the Consumer Product Safety Program, other Programs cover all these other excluded product categories.

Israel and Russia stated that while regulated products are controlled at a premarket stage, unregulated products controls may be limited to a post-market stage.

The role risk assessment in setting regulations or product standards

Thirteen jurisdictions noted that risk assessment plays an important role in authorities' decision to regulate or set a product standard, and in helping to determine steps to be taken. It should be noted that some of the jurisdictions indicated that they could not do so as the development of regulation or standards fell under the competence of other authorities.

Canada noted that all of the information in a risk assessment process helps to inform risk managers on the potential risk management measure needed which could include the development of a new regulation or use of product standards. Risk assessments can identify new types of hazards that an existing regulation or standard does not currently address.

France observed that dangerous products found on the marketplace or products that have been the cause of accidents may result in the implementation of regulations or standards in order to better control these products. Risk assessment based on accident scenarios is one of the elements that provide justification for a closer control of specific products.

The United States also reported that risk assessment drives consideration of rule-making and guides what measures are ultimately selected. Slovakia indicated that they would take into account the declared purpose of use of the product concerned.

Stage Two – Pre-market Controls

Product safety authorities often carry out proactive inspections at economic operators. The identification of unsafe products at the beginning of the supply chain (at the manufacturer, importer, or distributor level) can be very useful in stopping unsafe products from ever entering onto the marketplace and ending up in the hands of consumers. Some authorities carry out extensive inspections and, in some

instances, may undertake formal testing themselves, or require third party testing of products before they are brought on to the market. With reduced resources, however, many authorities are struggling to find some way to prioritise their work. Targeting the few economic operators who are often the ones responsible for a large amount of the unsafe products found in the marketplace can also be challenging, particularly acting prior to those products being introduced into the market. An example of the French approach to this issue is provided in Box 6.

Box 6. France’s risk assessment approach to target economic operators

France’s DGCCRF operates a “Contrôle de la Première Mise sur le Marché CPMM” (Initial Market Release Control), which aims to target economic operators at the source of product supply in France. A comprehensive inspection system is in place to assess a company’s ability to comply with applicable law and handle emergency situations. Companies are awarded a risk rating which will impact the frequency of subsequent checks.

What we learned from the responses to the survey

Pre-market approval of products

A few jurisdictions reported undertaking pre-market approval of products but they were in the minority. Singapore, for example, has pre-registration for certain controlled goods. Brazil (Box 7) and Colombia require large numbers of products to be certified before being placed on the market. Japan, Israel and Russia also reported that they have pre-market control. In the United States certain products subject to a federal consumer product safety requirement must be certified based on a test of each product or a reasonable testing program for compliance with applicable consumer product safety requirements. In the EU, only specific classes of products need to be approved before being placed on the market (e.g. drugs, automobiles). Some systems also require a more rigorous conformity assessment than suppliers’ declaration of conformity. This would include, for example, systems whereby a third party testing is carried out by a laboratory, as is the case in the EU with respect to certain products that are deemed to present a higher risk.

Box 7. Pre-market approval in Brazil

Inmetro regulates almost 600 different consumer products and services. The authority’s most frequent way to set a regulation for a product is based on a technical regulation associated to a third party mandatory conformity assessment procedure, called certification. The certification process is run by certification bodies and supported by testing labs. Both certification bodies and laboratories must be accredited by Inmetro, the Brazilian official accredited body. At the end of the certification process, the consumer product must be registered by Inmetro. Only after the registration can the company use Inmetro’s certification mark and be authorized to put the product in the market.

Stage Three – Border and Customs checks

With the increased market share of imported products, many product safety authorities now carry out checks at the border, in some cases in conjunction with customs authorities. Due to the volume of products arriving at ports of entry, one important issue is how to set priorities for the types of products to check and which actual shipments to stop and inspect. Some authorities have found it useful to collect information in order to profile individual economic operators and identify those whose products are more likely to be unsafe (Box 8).

Box 8. US CPSC's Risk Assessment Methodology (RAM)

The US CPSC's RAM aims to identify shipments having a high risk of containing violative products. The authority uses a live feed of data received from the Customs and Border Protection authority, which enables the CPSC to determine its own priorities and develop risk scores. Under the USA's Importer Self-Assessment (ISA) Product Safety Program, importers being qualified as "low risk" can apply for accreditation by the Customs authorities.

What we learned from the responses to the survey

Product safety checks at borders and customs

Only three jurisdictions did not report having product safety checks at their borders and customs. The three exceptions were from jurisdictions that undertake pre-market approval of products. This rendered border or customs controls irrelevant because the products were still being inspected. While most regulators do have the capacity for border checks for non-compliant products, they may not necessarily be part of normal ongoing operations, as in the case of Australia, which plans to pursue greater cooperation with its Australian Border Force agency in the immediate future.

Responsibility for border and customs checks

The best practice observed was where the product safety authorities retained responsibility for checks but may exercise this in conjunction with the customs authorities. Collaboration with the customs authorities seems to be necessary to have access to the necessary information to identify consignments of products. Risk profiles were cited as the basis for border and customs checks and many jurisdictions reported having annual programmes of activity.

How types of products are prioritised for checks

A majority of the responses indicated that the prioritisation of products was done on the basis of risk profiles. Slovakia, for example, explained that checks are carried out based on previous experience and on notifications received via the European Rapid Alert System for dangerous non-food products. In addition, the United States and Canada place a priority on regulated products. Box 9 provides a description of Canada's import surveillance system.

Box 9. Import surveillance in Canada

Health Canada's import surveillance is conducted in support of domestic surveillance. As a result, most non-compliance is being identified at the domestic level; import surveillance follows domestic compliance and enforcement actions. Prioritization for import surveillance is as follows:

- **Targets:** Shipments by specific companies that were identified as 'of concern' are flagged to be intercepted by the Canada Border Services Agency (CBSA) at Ports of entry for examination by Health Canada
- **Lookouts:** Categories of products are identified as 'banned' by Health Canada and as such, the CBSA are instructed to intercept such shipments when they encounter them during their normal work.
- **CBSA Pathfinder Data:** Health Canada receives a daily feed of 'post-release' data from the CBSA. This data consists exclusively of shipments that have already been released into Canada up to 30 days prior to receipt of the data. This data is used to identify companies with non-compliant product in the domestic marketplace.
- **Border Blitzes:** Inspectors conduct spot checks at ports of entry in collaboration with the CBSA. The goal of this activity is to focus on a range of commodities of interest both with and without supporting import data.

Focus is also on commercial importations. Consumers who inquire about the importation of products that are not intended for sale in Canada are advised that these products may not meet Canadian regulatory safety requirements and that the consumer may be taking on personal risk if they choose to import them.

Selection of specific shipments to check and the role of risk assessment in these checks

Risk profiles are also important in selecting specific shipments to check. Other factors included importer licensing and the U.S. RAM system. In Canada, when using CBSA targeting, shipments are prioritized based on 'targetable data elements'. These are elements that can automatically be triggered within the CBSA data platform (e.g. "business numbers" assigned to importers). The Border Service Officers (BSOs) of the CBSA will contact Health Canada when they encounter shipments of concern for Health Canada. These referrals are initiated by the BSO based on the targets, lookouts, or Health Canada information sessions designed to identify product safety issues of concern. The CBSA scan all containers entering Canada and request that Health Canada provide an admissibility recommendation for some shipments of consumer products and cosmetics.

Consideration of the economic operator related to a specific shipment and their previous history

Consideration of the economic operator is an emerging best practice in border and customs checks. The U.S. RAM tackles this issue. The Netherlands has a similar system in place and in Canada the compliance history of the regulated party involved is often taken into account. The Netherlands also intends (over the coming years) to pay special attention to improving data mining. The objective will be to optimise understanding of the trade flows and volumes of the relevant product groups, and the compliance behaviour of the players involved and the profiles of these players. In the case of Slovenia, the risk profile usually targets the specific importer or product type. This is defined when the risk profile is entered into the customs information system.

Systems to assess economic operators and their activities

With respect to the import of products the United States Importer Self-Assessment Product Safety (ISA-PS) system was the only one reported. The French CPMM system sets the level of inspections for economic operators established in France. In the EU, the European Commission is exploring how

compliance with EU harmonization legislation can be demonstrated/controlled electronically (“Digital Compliance” concept) in light of the fact that products are becoming more complex while the product cycles are becoming shorter.

Stage Four –Market Surveillance

Market surveillance is an important tool to help identify potentially unsafe products. Consumer complaints are in this context one of many sources of valuable information about potentially unsafe products, along with injury data. In addition, many authorities also proactively monitor markets, sample products, and test them. Due to limited available resources, authorities need to be able to identify where to devote their scarce resources. The first step is how to decide what action to take upon receipt of a complaint. They may then also wish to prioritise their market surveillance activities. Box 10 outlines Canada’s approach.

Box 10. Planned surveillance: Canada’s cyclical enforcement projects

Health Canada carries out market surveillance activities in a number of ways; planned inspections referred to as “cyclical enforcement (CE) projects” involve a review of specific product categories on a regular basis through product inspection, sampling and testing. Health Canada also takes a systematic approach to prioritizing its actions based on incidents reported to Health Canada related to consumer products. All incident reports received by Health Canada are triaged and routed for appropriate follow up, such as risk assessment, risk management, surveillance, and outreach to industry and consumers.

What we learned from the responses to the survey

Decision-making for actions on consumer products in the marketplace.

The concept of incident reporting is now mandatory in many jurisdictions. This means that economic operators are obliged to report incidents, in some cases even near-misses, associated with their products that might lead to some doubt being cast over their safety. Again, this is an example of a best practice that most jurisdictions have adopted. This often leads to a discussion about notification and frequently requires risk assessment to be conducted by the economic operator. The EU Alert Guidelines are geared up to assess the level of the risk posed by a specific product, in particular whether it rises to a serious product risk, which determines the type of notification to be sent by the authorities.

Planning of market surveillance activities

All the jurisdictions have market surveillance plans. Such plans are now required of European Member States on an annual basis and must be notified to the European Commission. PROSAFE’s Joint Market Surveillance Actions often provide the basis for much of the market surveillance plans, in particular for those smaller EU Member States lacking resources. In France, an annual planning of investigations aims to identify those products and practices requiring controls; the planning is assorted with a phase of consultation of the authorities concerned, taking into account all available data (such as accidents, consumer complaints, results of previous audits or other authorities, new regulations, expectations societal and / or media). The list of surveys in a specific year is generally determined in the autumn of the preceding year. Other interventions, motivated by reporting a dangerous product on the market, are not planned in advance but executed in response to the report.

In assessing overall compliance with mandatory standards and bans, the ACCC conducts extensive market surveillance including the purchase and commissioning of independent laboratory testing of products against performance and design requirements of the mandatory standards. Risk assessment drives

the ACCC's surveillance program whereby high risk products are more regularly targeted and assessed for compliance.

Role of risk assessment in planning market surveillance

Risk assessment is reported as playing an important part in planning market surveillance activities. In France, for example, risk assessment is performed at several levels: to plan product categories to target (choice of investigations); to select traders to control (choice of companies to visit for a given type of product); and to prioritize which product-specific model must be checked (selection of products to be examined in the various ranges and anticipate possible samples for analysis). Risk assessment of economic operators is also undertaken in the CPMM to determine the frequency of monitoring of the economic operators and the date of the next inspection. A further example of how market surveillance is directed at businesses in the Netherlands is provided in Box 11.

Box 11. Business-orientated surveillance in the Netherlands

Business-oriented surveillance focuses on encouraging compliance at these companies. In the Netherlands, this involves checking as many types of products as possible at the same company (Business-Oriented Product Surveillance, BOPS). Not only does this make the actual sampling process more efficient (one visit, several product groups sampled), it also produces a better picture of the company's compliance behaviour as a whole.

Another form of business-oriented surveillance that has grown massively is System Surveillance (SS). This involves using audits to check a company's quality system, if it has one and if this system is focused on assuring compliance with product safety legislation. Companies with a demonstrably well-functioning system are subject to less surveillance.

Written procedures and tools for risk assessment in market surveillance

One of the most important tools cited by survey respondents is the EU RAG online tool (described in Figure 3 above). PROSAFE's Book on Best Practice Techniques in Market Surveillance and guidance on the application of risk assessment in the European Rapid Alert System for dangerous non-food products have also been mentioned. PROSAFE is working on risk assessment templates for specific consumer products. The Czech Republic noted that it participates in the PROSAFE Risk Assessment group that has developed this guidance. The PROSAFE group also provides a rapid advice forum for market surveillance officials and develops model risk assessments for the products that are being targeted through the PROSAFE Market Surveillance Joint Actions. Germany also reported having its own market surveillance guidelines in addition to making reference to the EU alert guidelines and the PROSAFE Book on Best Practices.

Stage Five – Enforcement

Once a potentially unsafe product has been identified, many authorities use risk assessment to determine whether there is a need for enforcement action. There may be a legal threshold that has been established, such as a serious risk or a substantial product hazard that would trigger the need for enforcement action. If such action is needed, risk assessment may also play a role in determining what form that action should take. This could include product recall, sales ban, warning or voluntary action by the economic operator. The use of guidelines, such as in the EU (see Box 12), make the process more transparent and consistent.

Box 12. The European Union's rapid alert system

Under the European Union RAPEX rapid alert system, suspect products undergo a risk assessment to determine if the product presents a serious risk. Risk Assessment Guidelines have been developed for the use of the Member States. The methodology uses risk scenarios and probability factors. There is a formal notification obligation on Member States if a product presents a serious risk.

What we learned from the responses to the survey

The use of risk assessment to inform enforcement action

The European Rapid Alert System for dangerous non-food products is a very clear example of a system designed to determine the need for enforcement action. This was reported as being used by all the EU Member States and the candidate countries. The EU alert guidelines also contain a chapter (Chapter 4) entitled "From risk to action". The Japanese R-Map system is also very similar (these systems are illustrated previously in Figure 5).

Brazil also described its use of risk assessment to determine the types of enforcement actions to be taken when non-compliance with an appropriate regulation is found. The measures taken are categorised on the basis of the type of non-compliance (if they are low, medium, high, severe or critical). The risk to the consumer's safety (injury scenario, vulnerability of consumers, if there are complaints or any accident concerning the product) is taken into account as is the size of the company and the history of non-compliances. Other countries such as Israel, Japan, New Zealand, Russia and Singapore all acknowledged using the principles of risk assessment without having any specific systems in place. The United States noted that if prior intelligence is available, products could be seized at the border and destroyed if the U.S. Customs and Border Protection (CBP) does not authorise their export.

Objectives of risk assessment

The objective of risk assessment is to establish whether a product presents a risk at a specific level.

Evaluation of the effectiveness of the enforcement action(s)

Canada (Box 13), the EU Member States, Turkey, and Singapore indicated that they evaluated the effectiveness of enforcement action. Brazil does this by monitoring the history of the product and the company. The United States also indicated that feedback is given to their import control system RAM. Risk assessment would appear to play a role in the original choice of enforcement action.

Box 13. Recall effectiveness in Canada

Health Canada regularly assesses the effectiveness of proposed measures. When required, risk assessors may be requested to conduct an evaluation of how much the risk may be reduced or what a "safe limit" could be for an action. Specific to recalls, once they are published, the marketplace is monitored and the recalling establishment completes recall effectiveness checks.

The role of risk assessment in any evaluation

Brazil noted that if the level of non-compliance found is high, severe or critical, the products of the company concerned would be assessed more frequently during market surveillance actions. If it is an imported product, the shipments of the company concerned will be checked as many times as needed until

it is decided that the company's product complies to the appropriate regulation. In the United States, one of the underlying goals of the RAM is to mitigate risk associated with shipments of imported products in order to facilitate the movement of legitimate cargo.

The role of risk assessment in any communication activities that are undertaken as part of the overall risk management process

Risk assessment also plays a role in communications activities that are undertaken as part of the overall risk management process. For example, the result of the risk assessment could help identify the most appropriate channels of communication as well as the message. In Turkey, if the results of the risk assessment indicate a higher risk for a specific product group, the public is informed about this risk through brochures, announcements or with informational activities for specific risk groups. In addition to this, the measures should also be announced to the persons at risk by two national newspapers and two national television channels. Alternatively, announcement could also be through the local televisions, newspapers and direct informing methods, depending on the characteristics and size of persons affected by the risk. For New Zealand, inter-agency communications and communications with affected stakeholders are key. As a smaller economy, New Zealand perhaps has some advantages when it comes to dialogue, as it is relatively easy to build relationships and to hold face-to-face meetings. Singapore requires a website notice and an assessment to issue a press release and/or public notice for high-risk products with a score of above 80 in its Nomograph. In the Netherlands, communications such as public warnings are based in particular on the scenarios identified in the risk assessment. If consumer behaviour plays a major role, it is considered very important to inform the public about the risk.

Additional uses of risk assessment

The examples provided by the respondents generally related to the stages identified in the survey. For example reference was made to the assessment of economic operators, the safety of household electrical appliances, in support of setting standards and regulations and in the planning of activities. At least one jurisdiction stressed that all of its activities were risk-based. Another indicated that it was developing a risk based review process for product safety legislation involving referenced standards. There are therefore no uses of risk assessment to report in addition to what has already been stated.

Possible future work

This section describes survey participants' responses to a series of questions designed to gauge their interest in participating in any further work on risk assessment. It should however be noted that since the survey was carried out, and following the WP's 11th Session in October 2015, the WP Bureau agreed at its November 2015 teleconference meeting to suspend work on risk assessment for 2016 and the 2017-2018 biennium. What follows will therefore be used by the WP to re-assess its interest in any potential future work on risk assessment after 2018.

Challenges and opportunities

There are always challenges and opportunities in any activity government authorities undertake. While we may use risk assessment in a certain way now, we may wish to improve our best practices or the data we rely on. We may also wish to apply risk assessment in other ways than we do today.

What we learned from the responses to the survey***Use of risk assessment in new areas or activities***

Jurisdictions were asked to point to any new areas or activities which may be subject to risk assessment. A number of sectors were identified, including chemicals and the regulation of services and personnel. It was also suggested that there are areas where there is a lot of uncertainty that makes conducting a risk assessment more challenging. Examples included nanoparticles, endocrine disruptors, and product risk assessments that cover multiple chemicals/synergistic/interactive effects of chemicals.

Interest in learning more about specific risk assessment tools

Many jurisdictions indicated their interest in learning more about different risk assessment tools.

The need to develop specific risk assessment tools

A number of specific risk assessment tools that need to be developed were identified. These included tools for specific product groups such as chemicals, cosmetics and the safety of services. There was also a perceived need to make current tools more objective and to undertake more work on probability factors. One novel concept that was proposed was “non-conformity assessment”. It was suggested that this could lead to the statement that everything that is not in conformity with legislation is banned without any exception or leveling. This would then be easy to enforce and easy to understand.

Challenges and opportunities in the future in this field

The need for greater objectivity and for collaboration was highlighted. The European Commission noted that it remains a challenge to establish by a risk assessment whether the presence of a chemical in a particular product, considering the exposure, scenarios, etc., could result in a serious, less than serious or non-serious risk for the consumers. The safety of services and the cost of risk assessment were also highlighted in the comments as not included in the guidelines.

Future collaboration on the issues explored in this survey

It is hoped that the outcomes of this survey will help to identify common areas of interest or common gaps that may provide opportunities for multilateral collaboration, within or outside OECD. Accordingly, jurisdictions were asked to indicate their interest in participating with other jurisdictions in work related to the issues explored in this survey. The results are summarised in Table 8.

Table 8. Interest expressed in different issues

	Not interested	Interested	Very interested
Market Surveillance	0	2	14
Enforcement Action	0	5	9
Setting regulations and standards	1	7	8
Border and customs checks	1	10	4
Pre-market controls	3	5	4

As already discussed at a virtual symposium led by PROSAFE on market surveillance, the strongest interest is in the field of market surveillance, enforcement and setting regulations and standards. Rather less interest was expressed for pre-market controls. This likely reflects that the best practice in most relevant product sectors is moving away from mandatory certification and pre-market controls to suppliers' declaration of conformity monitored by post-market surveillance.

Future collaboration on issues identified previously during the workshops held by the WP

During the two risk assessment workshops and discussion at its meetings, the WP has identified some issues that could possibly be addressed in the future. As described in the explanatory memorandum that was attached to the survey (contained in Annex B to the present report), these included examining definitions of harm, quality of data, injury scenarios, probability factors, hazard coding and injury severity coding.

Current work

The EU is developing a general methodology for the assessment of risks presented by products in respect of all users and covering all risks, including those relating to the environment and to workers and professional users. This will complete and update the general risk assessment methodology available in the Guidelines for the management of the EU Rapid Alert System for dangerous non-food products so that they cover the other risks. A number of jurisdictions reported that they had on-going work in relation to the issues above including quality of data, injury scenarios and injury data, and probability factors. These initiatives are presented below.

Quality of Data

Canada is developing an approach to systematically and consistently rate the quality of the data used to characterize the risk. Similarly, the United States is also looking into the quality of data.

Injury scenarios and injury data

In Brazil, the Inmetro's Injury Surveillance System (SINMAC), based on consumers reports, works with injury scenarios. Inmetro is currently working on the procedure to validate the reports based on the definition of the coding of SINMAC. Generally speaking, Brazil is currently working on the redesign of its operational processes in order to improve knowledge and skills on these issues. Brazil is also working on

reducing the risks associated with lack of sufficient information for decision-making throughout the regulatory process.

Canada is planning to provide more guidance to its risk assessors on how to establish injury scenarios. Israel is planning to sign agreement with the Israel Trauma Research Center that will supply the Israeli authorities with data from a number of large hospitals. They will obtain Emergency Room figures on products that have caused bodily injury or death. The information will help them set market surveillance priorities.

Probability factors

In the Netherlands the Consumer Safety Institute has recently been commissioned to analyse the possibilities for improving the risk assessment process, in particular focussing on the probability factors. This project will be finalised by the end of this year. The Dutch plan to ask for input from colleagues in other countries during the project. In addition they are working on proposals to define the risk levels including “serious risk” for chemicals in consumer products. The United States is also looking into probability factors. Canada has developed a risk characterization methodology that sets out a method to characterize risks posed by various types of products on a comparable scale (considering hazard and likelihood). This characterization, regardless of the nature of the hazard, generates a risk level that is comparable across all risk areas (toxicological, electrical, mechanical, and flammability hazards).

Possible co-operation with other jurisdictions

One of the objectives of the survey was to help inform the WP’s decision about future work on risk assessment jurisdictions. Participants were therefore asked to indicate their interest in participating with other jurisdictions in work related to the issues previously identified by the WP. The results are summarised in Table 9, which shows strong interest in exploring issues related to the quality of data, probability factors and injury scenarios; a lower level of interest was expressed in hazard and injury severity coding for which more established procedures are in place.

Table 9. Interest in participating in work with other jurisdictions

	Not interested	Interested	Very interested
Quality of Data	0	5	10
Probability Factors	0	8	8
Injury Scenarios	0	9	7
Hazard Coding	1	11	4
Injury Severity Coding	1	9	4

Other possible future work at the international level

Jurisdictions were also asked to indicate any other work they considered it might be useful to undertake at the international level. Brazil proposed work involving the improvement of data quality and database integration, as well as on improving the understanding of indicators for risk management and cooperation on market surveillance activities. Other proposals were for more enforcement cooperation and more systematic information sharing between peers. The creation of a worldwide database from hospitals

on products that have caused bodily injury or death was also proposed echoing the efforts the WP is making in this regard. Attention was drawn again to the need to undertake work on the safety of services and on the need for a harmonised approach to physical and chemical risks.

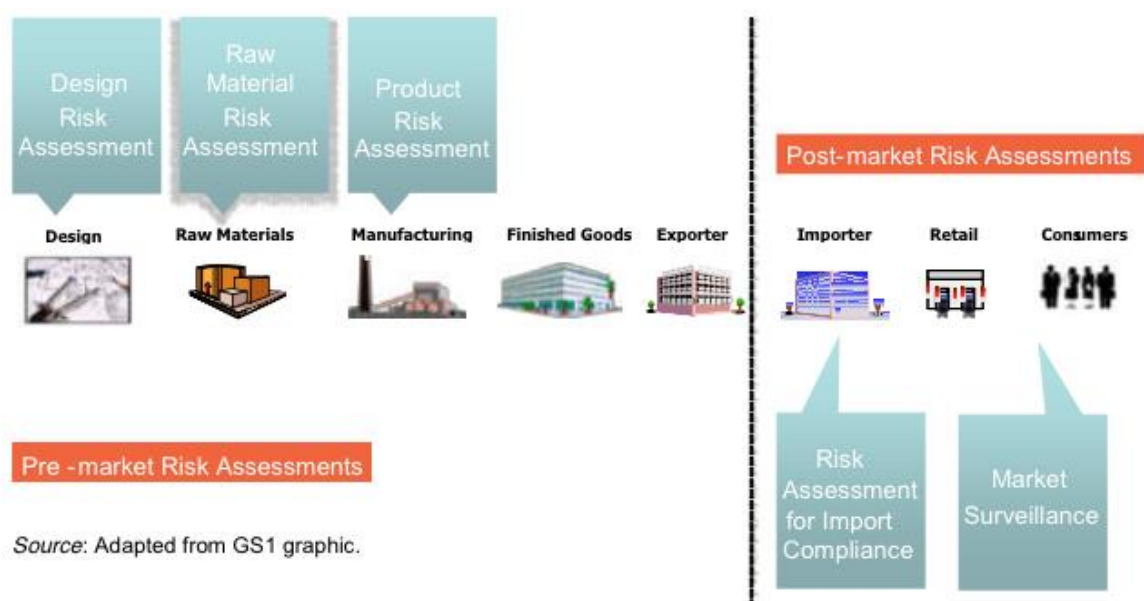
ANNEX A
SURVEY OF INTERNATIONAL CONSUMER PRODUCT SAFETY RISK ASSESSMENT PRACTICES
[\[DSTI/CP/CPS\(2015\)11\]](#)

Background

The OECD Working Party on Consumer Product Safety has held two Risk Assessment Seminars; one in Israel in 2012 and the other in Australia 2013. A report was developed based on the outcome from these two workshops [[DSTI/CP/CPS\(2014\)6/FINAL](#)]. The focus of these workshops was largely product risk assessment. However, what was also evident from the discussions during and after the workshops was that authorities use risk assessment as a tool to help inform a number of decisions they need to make at different stages of the product safety cycle.

Health Canada proposed a study to examine this aspect during the October 2014 Working Party (WP) meeting through a survey of OECD members. The survey before you now has been designed to help promote a broader understanding of how authorities use risk assessment to inform their decision-making. The results of this survey could be taken into account by the WP as it seeks to establish priorities for its future work.

Introduction to the survey



The diagram above illustrates the fact that risk assessment is used at different stages of the supply chain by both business and authorities. The findings of the two OECD Risk Assessment workshops suggested that risk assessment has different meanings across different jurisdictions. The idea of the study is to take a broader view of risk assessment and look at the assessment of risks by authorities at different stages of the product safety cycle. This should not be only related to products but also to economic operators. We want to identify new areas and tools that the WP may wish to address in the next phase of its work on risk assessment

We encourage you to provide as much information as you can

Although some of the questions we ask could simply be answered with a “yes” or “no” we would encourage you to provide further explanation. This may be in the form of written materials.

Terms used in this survey

It is quite difficult to avoid using risk-related terms in the survey, which have specific meanings in different jurisdictions. To help facilitate a common understanding of the concepts and terms used, we have provided some explanations throughout the survey, along with many examples of the kinds of uses of risk assessment that we are hoping to identify.

How the information from the surveys will be used

The responses to the survey will be used to draft a report that will be presented to the OECD Working Party. The Working Party may decide in due course to make the final report public. The responses to the survey will only be stored on the WP's workspace in the regulators-only section.

Deadline

Please return to Health Canada's contractor Bruce Farquhar at brucejfarquhar@yahoo.ca before Monday April the 20th. If you have any questions concerning the survey, please direct them to Bruce Farquhar.

We would like to take this opportunity to thank you in advance for taking the time to complete this survey!

SECTION ONE: RISK ASSESSMENT AND RISK MANAGEMENT IN YOUR ORGANISATION

Risk assessment and risk management are two key concepts in product safety. *Risk assessment* is a systematic process of evaluating the potential risk posed by a product in order to inform decision-making. *Risk management* is a term used to collectively describe the activities and considerations involved in addressing and communicating information about risks under conditions of uncertainty. Risk management generally includes a number of inter-related activities such as: risk identification, risk assessment, risk mitigation and risk communication.

Case Study

Health Canada's Consumer Product Safety Program defines risk assessment and other important risk assessment terms and concepts in its Risk Assessment Framework. The Program tries to keep risk assessment determinations and decisions on risk management actions separate. Risk assessments are conducted by risk assessors who make a determination with respect to the risk level associated with a product. These conclusions are then used by risk managers within the Program to determine what, if any, risk measure is needed. Risk measures take into consideration factors such as public perception, availability of the product, political pressures, etc. Such factors may be part of the "risk assessment" in other jurisdictions.

1. How do you define risk assessment? Is this definition laid down in your legislation, guidance documents, operating procedures, or other documentation?

2. How do you define risk management? Is this definition laid down in your legislation, guidance documents, operating procedures, or other documentation?

3. Are your risk assessment and risk management processes separate? This could be in terms of how they are laid down in policies or procedures or in how they are implemented practically, for example, by different parts of within your organisation.

4. What kinds of considerations inform your risk assessment process? (I.e. what factors do you take into account when assessing risks?)

The way the product is used? YES/NO – delete as applicable

How widespread the use of product is? YES/NO

Whether the product is new? YES/NO

The accessibility of the product once purchased? YES/NO

The level of perceived risk by consumers? YES/NO

Whether the product could impact a vulnerable consumer group? YES/NO

Is it attractive to a specific risk group? YES/NO

Are there multiple types of potential exposure to consider? And related levels of toxicity? YES/NO

Whether the instructions and warnings clear? YES/NO

Injury scenarios? YES/NO

The severity of injury and potential health effects?YES/NO

Probability of harm occurring?YES/NO

Please identify any other factors not listed above

5. What kinds of considerations inform your risk management process? (i.e. What factors do you take into account when selecting and implementing options to manage risks?)

6. Do you have written procedures or guidance documents for risk assessment or risk management?

7. Do you use any specific risk assessment tools¹⁵? If so, please provide further details,

8. Have you identified any specific risk assessment tools¹⁶ that might be useful to your organization or to others? If so, please provide further details,

9. Do you have any system to classify or code hazards?

10. Do you have any system to grade or code the severity of injuries?

11. Are there definitions or defined terms you use in the risk assessment process? If so, please reference the documents in which they may be found.

SECTION TWO: HOW DO YOU ASSESS RISKS AT DIFFERENT STAGES OF THE PRODUCT SAFETY FRAMEWORK?

Note: The following section poses a series of questions about assessing risk at different stages of the product safety cycle. If responsibility for these different stages lies with your colleagues, please ask them to assist you to complete the relevant section(s) of the survey.

Stage One – Legislating, regulating and setting standards

Many jurisdictions have some form of general safety requirement for consumer products. Within those systems there is sometimes a need to establish product-specific regulations or standards. Based on these regulations and standards, some product safety authorities will approach regulated and unregulated products (products without specific regulations) differently when determining how to approach certain aspects of their work.

¹⁵ For the purposes of this survey, a tool can be defined as any checklist, form, table, algorithm, application/program or resource that assists your organization in making a determination of risk.

¹⁶ Please see footnote above.

Case Study

- The Consumer Product Safety Act is the umbrella statute of the United States Consumer Product Safety Commission (CPSC). The Act requires that prior to promulgating a consumer product safety rule, the Commission shall consider, and shall make appropriate findings for inclusion in such rule with respect to the degree and nature of the risk of injury the rule is designed to eliminate or reduce. This provision requires in practice a formal risk assessment.

Questions

1. Do you have a general safety requirement?
2. Do you set regulations or products standards for specific products?
3. Do you differentiate during your activities such as market surveillance and enforcement between regulated and unregulated products?
4. What role does risk assessment play when you are deciding whether to regulate or set a product standard?
5. Do you take into account in any risk assessment you carry out any factors that you have not already identified under section one of this survey?

Stage Two – Pre-market Controls including Inspections at Economic Operators

Product safety authorities will often carry out proactive inspections at economic operators. The identification of unsafe products at the beginning of the supply chain (whether it be at the manufacturer, importer, or distributor) can be very useful in stopping unsafe products ever entering onto the marketplace and ending up in the hands of consumers. Some authorities will carry out extensive inspections and may even undertake formal testing themselves, or require third party testing of products before they are brought on to the market. With reduced resources, however, many authorities are struggling to find some way to prioritise their work. Targeting those few economic operators who are often responsible for many of the unsafe products that reach the marketplace in advance can also be challenging.

Case study

French authorities operate a system called “Contrôle de la Première Mise sur le Marché CPMM” (Initial Market Release Control). This system targets economic operators at the source of product supply in France. There is a comprehensive inspection that assesses a company’s ability to comply with applicable law and handle crisis situations. Companies are awarded a risk rating and the frequency of subsequent checks depends on the rating.

Questions

1. Do you have a system for pre-market approval of products?
2. If a system exists, can you briefly describe the system and explain how the risk of a product is assessed? The questions below might help you.
3. Who carries out the risk assessment?
4. What factors must they take into account? Please identify any factors that you have not already identified under section one of this survey.

Stage Three –Border and Customs checks

With the increased market share of imported products, many product safety authorities now carry out checks at the border. This may be done in conjunction with customs authorities. Due to the volume of products arriving at ports of entry, one important issue is how to set priorities for the types of products to check and which actual shipments to stop and inspect. Some authorities have found it useful to collect information in order to profile individual economic operators and identify those whose products are more likely to be unsafe.

Case Study

The U.S. CPSC RAM (Risk Assessment Methodology) has as its objective the identification of shipments having a high risk of containing violative products. CPSC receives a live feed of data from Customs and this allows the CPSC to determine its own priorities and develop risk scores. The Importer Self-Assessment (ISA) Product Safety is a scheme whereby importers can apply for accreditation under the program that labels them “low risk”.

Questions

1. Are there product safety checks carried out at your nation’s borders or customs?
2. Who carries these checks out?
3. How do you decide what types of products to prioritise for checks?
4. How do you decide which specific shipments to check?
5. Do you consider the economic operator related to a specific shipment and their previous history?
6. What role does risk assessment play in these checks?
7. Do you use risk assessment to evaluate economic operators?
8. Do you have a system like the Importer Self-Assessment (ISA) referred to above that allows economic operators to undergo assessment of their activities?
9. Do you take into account in any risk assessment you carry out any factors that you have not already identified under section one of this survey?

Stage Four –Market Surveillance

Market surveillance is an important tool to help identify potentially unsafe products. Consumer complaints are one of many sources of valuable information about potentially unsafe products. Another valuable source of information is injury data. However many authorities also proactively go out into the marketplace, sample products, and test them. Due to limited available resources, authorities, have to be able to identify where to devote their scarce resources. The first step is how to decide what action to take upon receipt of a complaint. They may then also wish to prioritise their market surveillance activities.

Case Study

Health Canada carries out market surveillance activities in a number of ways; planned inspections referred to as “cyclical enforcement (CE) projects” involve a review of specific product categories on a regular basis through product inspection, sampling and testing. Health Canada also takes a systematic approach to prioritizing its actions based on incidents reported to Health Canada related to consumer products. All incident reports received by Health Canada are triaged and routed for appropriate follow up, such as risk assessment, risk management, surveillance, and outreach to industry and consumers.

Questions

1. How do you decide whether to take action or not in respect of a product already on the marketplace?
2. What role does risk assessment play in your decision?
3. How do you plan your market surveillance activities? What role does risk assessment play in your planning?
4. Do you take into account in any risk assessment you carry out any factors that you have not already identified under section one of this survey?
5. Do you have any written procedures or tools that help you when using risk assessment in your market surveillance work?

Stage Five –Enforcement Action

Once a potentially unsafe product has been identified, many authorities use risk assessment to determine whether there is a need for enforcement action. There may be a legal threshold that has been established, such as a serious risk or a substantial product hazard, that would trigger the need for enforcement action. If such action is needed, risk assessment may also play a role in determining what form that action should take. This could include product recall, sales ban, warning or voluntary action by the economic operator.

Case Study

Under the European Union RAPEX rapid alert system, suspect products undergo a risk assessment to determine if the product presents a serious risk. Risk Assessment Guidelines have been developed for the use of the Member States. The methodology uses risk scenarios and probability factors. There is a formal notification obligation on Member States if a product presents a serious risk.

Questions

1. Do you use risk assessment to determine the need for enforcement action and/or to identify what enforcement action should be taken?
2. What is your objective when you are assessing the risk presented by a specific product? Are you trying to establish whether the product presents a risk at a specific level (e.g. a substantial product hazard or a serious risk)?
3. Do you evaluate the effectiveness of the potential enforcement action(s)?
4. If so, does risk assessment play any role in this evaluation?
5. Does risk assessment play a role in any communications activities that are undertaken as part of the overall risk management process?
6. Do you take into account in any risk assessment you carry out any factors that you have not already identified under section one of this survey?

Other stages – Additional uses of risk assessment in your activities

The stages we have listed above are some examples of different ways risk assessment may be used by authorities. If you use risk assessment in other ways please let us know.

Questions

1. How else do you use risk assessment?
2. What are your objectives?
3. Do you have any written guidance for this use of risk assessment?
4. Do you take into account in any risk assessment you carry out any factors that you have not already identified under section one of this survey?

SECTION THREE: FUTURE WORK

While the aim of this survey is get a better understanding of current practices, when considering its future work, the OECD WP will want to understand the type of RA capacity/tools members' may want to build in the future, or what tools they would like OECD WP to consider developing sooner rather than later to help support their RA. It will also be important if the OECD WP is to move forward to set priorities amongst these activities.

Challenges and opportunities

There are always challenges and opportunities in any activity we undertake. While we may use risk assessment in a certain way now, we may wish to improve our best practices or the data we rely on. We may also wish to apply risk assessment in other ways than we do today.

Questions

1. Would you like to use risk assessment in areas or activities where you currently do not use it?
2. Would you like to learn more about specific risk assessment tools?
3. Are there any needs to have specific risk assessment tools developed?
4. What challenges and opportunities do you see in the future in this field?

Future Collaboration on the issues explored in this survey

The outcomes of this survey may identify common areas of interest or common gaps that may provide opportunities for multilateral collaboration, inside or outside of the OECD WP framework.

1. Would you be interested in participating with other jurisdictions in work related to risk assessment applied to those issues explored in this survey?

Please indicate your interest below

	Not interested	Interested	Very interested
Setting regulations and standards			
Pre-market controls			
Border and customs checks			
Market Surveillance			
Enforcement Action			

Future Collaboration on issues identified previously by the WP

The WP has identified, through the two previous workshops and discussion at the WP meetings, some issues that could be addressed in the future. These issues include examining definitions of harm, quality of data, injury scenarios, probability factors, hazard coding and injury severity coding. For further information please see the explanatory memorandum that came with this survey.

Questions

1. Are you already working on some of these issues? If so please list them below and explain a little about what you are doing?
2. Would you be interested in participating in work on these issues with other jurisdictions?

Please indicate your interest below

	Not interested	Interested	Very interested
Definition of Harm			
Quality of Data			
Injury Scenarios			
Probability Factors			
Hazard Coding			
Injury Severity Coding			

3. What other work do you think it would be useful to undertake internationally?

Thank you for completing this survey!

Submission of completed survey

Please return the completed survey to Health Canada’s contractor Bruce Farquhar at brucefarquhar@yahoo.ca before Monday April 20, 2015.

Written materials

If you have any written materials that relate to any of your answers to this survey please send them with your completed survey. All materials sent will be compiled and made available on the regulators section on Clearspace.

ANNEX B INTERNATIONAL DEFINITIONS USED IN RISK ASSESSMENT

Bosnia and Herzegovina

Risk assessment: A procedure that is applied by the market surveillance officers to determine the level of risk posed by a specific product to health and safety of consumers (The definitions used for risk assessment of products are laid down in the **Instructions for risk assessment** which is in the phase of the adoption by Council of Ministers of Bosnia and Herzegovina).

Risk management: Risk management is considered as a procedure that is used to decide upon measures considering the results of the risk assessment. The risk management procedure is specified in the Standard Operating Procedure.

Brazil

Risk assessment: Overall process of risk identification, risk analysis and risk evaluation (ABNT ISO Guide 73:2009 – Risk management-- vocabulary – item 3.4.1)

Risk management: Systematic application of management policies, procedures and practices to the tasks of communicating, consulting, establishing the context, identifying, analyzing, evaluating, treating, monitoring and reviewing risk (ABNT ISO Guide 73:2009 – Risk management--- vocabulary item 2.2)

Inmetro uses the ISO 31000 family standards as reference documents.

Canada

Risk assessment: A systematic process of evaluating the potential risk posed by a product in order to inform decision-making.

Risk management: A term used to collectively describe the activities and considerations involved in addressing and communicating information about risks under conditions of uncertainty.

Foreseeable use: Any use or misuse of the product that could be reasonably foreseen, and will often exclude gross negligence, or criminal activity.

Harm: An injury, adverse health effect, loss of life, or any combination of these outcomes.

Hazard: A substance, product, human activity, condition, or situation that is a potential source of **harm** to human health or safety (adapted from ISO Guide 51).

Near Miss: An occurrence that could have resulted in harm, or in a greater degree of harm, under different circumstances.

Risk: The effect of exposure to a hazard on human health or safety, which integrates the likelihood of occurrence of possible outcomes with an estimate of the magnitude of the associated severity of these outcomes.

Risk Characterization: The final component of a risk assessment in which the level of risk is estimated according to the likelihood and the severity of the potential impact.

User: Broadly defined to include persons affected by the product, including bystanders who may be exposed to the product.

Uncertainty: Imperfect or incomplete information that results in the inability to derive a precise estimate of the level of risk.

Variability: The range of characteristics among a population that may be exposed to a risk, and that should be taken into consideration when risks to that population are assessed and/or mitigated.

Czech Republic

Risk assessment: Assessment of potential risks that can be posed by (use of) a consumer product. (Czech Trade Inspection Authority (market surveillance in the Czech Republic) internal operating procedures.)

Risk management: Adopted compulsory measures (e.g. Ban on the marketing of the product and any other accompanying measures).

Denmark

Risk assessment: Defined as per RAPEX Guidelines

Risk management: Defined as per RAPEX Guidelines

European Union

Risk assessment: The European Commission in its ‘EU alert guidelines’ define the risk assessment methodology for EU Member State authorities to perform in order to assess whether a product poses serious risk to the health and safety of consumers and if it needs to be notified to the European Rapid Alert System for dangerous non-food products. The methodology assist in assessing the level of risk the product can pose.

The risk assessment is a procedure which in order to identify and assess hazards, consists of three steps:

- Identification of the seriousness of a hazard,
- Determination of the probability that a consumer will be injured by that hazard,
- Combination of the hazard with the probability.

Risk management: follow-up action, which is separate from risk assessment and aims to reduce or eliminate a risk. This is also defined by the above mentioned ‘EU alert guidelines’

EU alert guidelines **Glossary of terms**

Hazard: Source of danger involving the chance of being injured or harmed. A means of quantifying the hazard in a risk assessment is the severity of the possible injury or harm.

Product hazard: Hazard created by the properties of a product.

Risk: Balanced combination of a hazard and the probability that damage will occur. Risk describes neither the hazard, nor the probability, but both at the same time.

Risk level: Degree of risk, which may be ‘serious’, ‘high’, ‘medium’ and ‘low’. When the (highest) level of risk has been identified, the risk assessment is complete.

Finland

Risk assessment: A risk defining process which combines risk analysis (hazard identification and the probability of the hazard/harm multiplying the consequences of the hazard/harm) and risk evaluation ("significance of risk" recognizing the user group of the product in question, the circumstances in which the product is likely to be used, the intended use).

The definitions used are equal to the standard SFS-IEC-60300-3-9.

France

Risk assessment: Évaluation des risques : procédure visant à identifier et à quantifier la combinaison d'un danger et de la probabilité que celui-ci occasionne des dommages. (Cette définition appartient aux procédures officielles mises en œuvre à la DGCCRF.)

Risk management: Gestion des risques : action de suivi visant à éliminer un risque ou à le réduire à un niveau acceptable (Cette définition appartient aux procédures officielles mises en œuvre à la DGCCRF.)

Germany

Risk assessment: Risk Assessment in the field of consumer products refers to the definitions of GPSD and RAPEX. For other product sectors also other sources are used eg. ISO 12100 et al.

Risk management: Risk management take place after the RA process and contains the decision, what to do with the information about the risk level.

Japan

Risk assessment: A process of enhancing the safety of a product by specifying a hazard or a hazardous situation expected to be caused in possible usage conditions, evaluating the magnitude of its impact and then incorporating measures against it into product design in advance. Although this definition is not specifically laid down in legislations, handbooks are published about risk assessment mainly for manufacturers and importers in 2010 and 2011.

http://www.meti.go.jp/product_safety/recall/risk_assessment.html.

Netherlands

Risk assessment: The process that estimates the risk that a product with dangerous properties poses to people, animals or property. (The definition used in the EU RAPEX Guidelines (2010) and the Prosafe book “Best Practice Techniques in Market Surveillance” (2009)). In addition, the Netherlands has a separate law dealing with the independent risk assessment by the Food and Consumer Product Safety Authority (Law of April 26, 2006). This law defines risk assessment as a science-based process comprising four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

Risk management: The process intended to control the risk. This may involve any proportionate and adequate measures including, e.g. banning the sale of the product and communication to the public. (In the Prosafe book “Best Practice Techniques in Market Surveillance” (2009)).

The Russian Federation

Risk assessment: A systematic definition of risk arising possibility and breaking consequences (Definition from the Customs code of the Customs Union)

Risk management: A systematic work on creation and practical realization of measures on prevention and minimization of risks, on estimation of their application effectiveness, and also on control of customs operations, providing a continuous updating, analysis and reconsideration of information available to customs bodies (Definition from the Customs code of the Customs Union)

Singapore

Risk assessment: In the context of product safety, risk assessment is the determination of quantitative or qualitative value of risk related to a situation and a recognized hazard, or of how unsafe a non-compliance product is. This is documented in our internal reference documents.

Risk management: Risk management is the process to be taken after the risk assessment has been conducted. For new products, it is the type of conformity assessment system determined for the various risk level of the products, low risk products will be subjected to type testing and high risk products may be subjected to increased market surveillance. For findings from market surveillance activity, the risk assessment of the product failure is used to determine the type of corrective actions to be taken by the suppliers.

Slovenia

Risk assessment: As defined in the Commission decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System ‘RAPEX’ established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive), OJ EU L22, 26.1.2010 (COM Guidelines).

Risk management: As defined in the Commission decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System ‘RAPEX’ established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive), OJ EU L22, 26.1.2010.

Turkey

Risk assessment: The Regulation on “Record and Notification of Market Surveillance Activities and Measures” defines” risk assessment” as “a process to determine the degree of risk posed by a product by using a methodology”. This methodology is a part of the “Risk Assessment Guideline” referred to in the Regulation. This Guideline is the translation of the “Risk Assessment Guideline for Consumer Products (RAPEX Guidelines) and shared with MS Authorities under this Regulation. In the guideline, risk assessment is defined as a procedure for identifying and assessing hazards, consisting of three steps, which are “identification of the seriousness of a hazard”, “determination of the probability that a consumer will be injured by that hazard” and “combination of the hazard with the probability”.

Risk management: Risk management is defined in the “Risk Assessment Guideline” as a follow-up action, which is separate from risk assessment and aims to reduce or eliminate a risk.

United States

Risk assessment: A systemic process of evaluating and determining the quantitative or qualitative value of risk related to an activity or undertaking.

Risk management: The identification, assessment, and prioritization of risks followed by the coordinated application of resources to reduce, minimize, monitor, and control the probability and/or impact of undesirable events.

Additional definitions can be found in the CPSC Strategic Plan (risk factors and mitigating plans at this link: <http://www.cpsc.gov/PageFiles/112082/2011strategic.pdf>) with Injury terms defined in http://www.cpsc.gov/Global/Neiss_prod/completemanual%20.pdf.